

ORGAN DONATIONS

HEARINGS
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED FIFTH CONGRESS
SECOND SESSION

SPECIAL HEARINGS

SEPTEMBER 10, 1998—WASHINGTON, DC
SEPTEMBER 12, 1998—SCRANTON, PA

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ORGAN DONATIONS

THURSDAY, SEPTEMBER 10, 1998

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter, Faircloth, and Murray.
Also present: Senators Santorum and Torricelli.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

**STATEMENT OF DONNA SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES**

OPENING REMARKS OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. It is precisely 10 o'clock, and we will begin this hearing of the Subcommittee on Labor, Health and Human Services, and Education of the Appropriations Committee.

Without objection, since I am the only Senator here, except for our witness, my full statement will be placed in the record. We have a very tight timetable and have to be concluded by 11 o'clock.

Our subject matter today is the issue of organ transplants, and we are dealing here with a regulation issued by the Department of Health and Human Services, which would essentially establish priority based on need without regard to geography.

PREPARED STATEMENT

We have a provision in the House of Representatives Appropriation Committee report—it has not reached the House floor yet—which would delay that for a year. The subcommittee, which was marked up in the full committee on the Senate side, has no such limitations.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ARLEN SPECTER

The subcommittee will come to order. Today the Labor-HHS subcommittee convenes this special hearing to discuss the proposal by the Department of Health and Human Services to change the prioritization system that determines which patients on a waiting list would receive a donated organ.

This has been an important issue on this bill. The House included language in the fiscal year 1998 supplemental bill to delay implementation of these changes until October 1, 1998. In their version of the fiscal year 1999 Labor-HHS appropriations bill, the House included language to further delay the changes until November 1, 1999.

Because of a chronic shortage of available organs, these decisions are critical to those who may have only days or even hours to live unless an organ is found, as well as to those who suffer from a chronic but no less debilitating illness. It has been estimated that 57,000 people are on an organ donor waiting list somewhere in this country and that 500 new patients are added to the lists each month. In contrast there were only 5,400 donors in 1996.

Managing a shortage of this magnitude causes great anxiety among patients, their families, and their doctors. It is a zero-sum situation—giving to one takes away from another. A central answer to this dilemma is to increase the numbers of individuals who choose to be a donor. Because of the urgency to increase donations, the Senate version of the appropriations bill triples funding for organ donation activities from \$2.8 million last year to \$10 million. That more than doubles the administration's budget request for this program.

In the meantime, Secretary Shalala has the difficult task of proposing a fair method to deal with the shortage. This hearing will examine the underlying reasons and assumptions of the proposal and its implications for patients and their families.

Today we will have two panels, the first one with Donna Shalala, distinguished Secretary of the Department of Health and Human Services. The second panel includes: Mr. Craig Irwin of the National Transplant Action Committee, Dr. Charles Miller of the Mount Sinai Medical Center, Dr. Ronald Busuttil of the American Society of Transplant Surgeons, and Dr. William Pfaff of the United Network for Organ Sharing.

The subcommittee will also be holding a field hearing on this topic in Scranton, Pennsylvania this Saturday. We will have former Governor Bob Casey, a transplant recipient himself, and two other patients as witnesses who can testify in personal terms about waiting for a donated organ.

Before Secretary Shalala begins her opening statement, the subcommittee will hear brief statements from Senator Robert Torricelli of New Jersey and Congressman Ron Klink from Pittsburgh.

Senator Torricelli, you may begin.

To ensure that we have sufficient time for questions and answers, we ask that each witness limit their opening remarks to 5 minutes. Your full statement will be included in their entirety in the appropriate place in the record.

ADDITIONAL PREPARED STATEMENTS

Senator SPECTER. Senator Ford, Senator Kerrey, and Congressman Klink were unable to attend the hearing today, they have submitted statements which we will insert into the record at this point.

[The statements follow:]

PREPARED STATEMENT OF SENATOR WENDELL FORD

Let me begin by thanking you for the opportunity to express the Kentucky transplants community's concerns in today's hearing. I know that everyone here is equally concerned with assuring that liver transplant patients are treated with fairness and dignity.

Unfortunately, today's hearing and the motivation behind the hearing have sent up a red flag in much of the transplant community. With good reason, they are concerned this hearing will add fuel to an emotional issue drawing attention away from what should be everyone's main concern—patients. A battle between HHS and Congress over who ultimately decides transplant policy places patients and the UNOS process in jeopardy.

Many of us are very concerned that in an effort to review policy and nationalize the organ allocation system, HHS will decrease the access to transplant centers around the country.

I certainly understand the position of larger centers who have seen their performance levels drop. But their drop in numbers has a positive side to it. It means that medium and smaller transplant centers across the country have developed the knowledge and expertise to treat the medically underserved in their area.

In fact, that change has made a tremendous impact on states like my own. Only 13 Kentuckians underwent liver transplantation in 1988 as compared to 38 performed through August of this year. This represents nearly a 300-percent increase. Yet, it does not represent either a population explosion or a sudden increase in the incidence of liver disease. We've saved more Kentucky lives because of the increased accessibility to transplant centers located in the Commonwealth as well as the centers' own efforts to increase organ donations. The Commonwealth is proof of the success of local primacy in organ donations and allocation.

Most of the patients undergoing transplantation at our local centers are indigent. They do not have the means nor the ability to travel with their families to a large metropolitan area. This is compounded by the fact that transplantation often requires spending months at the location before and after transplantation. Increasing the number of transplant centers has removed what were once daunting obstacles for many patients.

HHS's recent proposal will have a far reaching effect on the organ program in this country. It's imperative that HHS recognize and listen to the transplant community before a national organ allocation policy is established.

I have heard from many of my constituents including Cheryl Geiger, a transplant patient, who wrote: " * * * how are patients and their families supposed to pay for the costs associated with having to travel to a transplant center in another state? This policy change favors the wealthy. People who cannot afford to travel to distant transplant centers will end up foregoing the opportunity." She is not alone, Alice Melkovitz was listed 3 times at a Pittsburgh facility, but was sent home because of problems with her insurance.

In a recent letter to Members and again in her statements during the Joint Congressional hearing on June 18th, Secretary Shalala stated, "the medium waiting times for the two major liver transplant centers in Kentucky were vastly different—38 days at one center, 226 at the other." According to the University of Kentucky Medical Center this information is outdated and incorrect. Recent statistics indicate that the waiting time between the two programs is two days; 154 days in one and 156 days in the other.

Secretary Shalala has yet to respond to my letter disputing her comments. But it is my strong belief that inaccurate information makes it difficult to determine what impact the HHS regulation will have on smaller and medium transplant centers. By all means review. But don't jeopardize a system that has grown over the past 10 years into a generally successful, responsive and most importantly, equitable service for thousands of Americans.

I believe Secretary Shalala has done an excellent job in leading HHS. However, I do not believe there is justification for changing the organ allocation policy. Everyone in the transplant community has a common goal—to save lives. Our top priority should be to increase the number of organ donations. To do that, we need to be sure any policy changes and tinkering with the system doesn't end up having a negative impact on this shared goal.

In closing, let me say that until we have as many organ donors as we have needs, the system will not be perfect. But regardless of how good HHS's intentions might be, preemptive federal action may have the undesirable effect of not only undermining UNOS efforts on behalf of liver transplantations, but for other types of organs as well.

Thank you.

PREPARED STATEMENT OF SENATOR J. ROBERT KERREY

Mr. Chairman, I welcome the opportunity to share my views on organ allocation. I am pleased that this Committee is contributing to public debate on this important issue.

It is obvious to me that our current organ allocation system does not work. Our transplant centers have established an enviable list of success stories, but the approximately 4,000 people who die each year waiting for an available organ are not able to share in this success. I am particularly troubled by the geographic disparities in waiting times, which range from five months to twenty-eight months for white liver recipients. This variation means that whether you live or die can be determined by where you live, or where you list, not by your medical need or your prospects for a successful transplant.

Transplant recipients are our children, our neighbors and our friends. I want to briefly share two Nebraska transplant stories with you—one long-delayed success, and one tragic death.

First, Shante Smith is a four-year-old Nebraskan who loves to dance and eat pizza and onion rings. She has also had two small bowel transplants at the University of Nebraska Medical Center. Between her two transplants, Shante waited a total of 634 days for a small bowel donor. She is now recovering after her latest transplant.

Next, I want to highlight Justin Parker, an Illinois baby who died at UNMC while waiting for a liver and small bowel transplant. Justin's irreversible liver damage was a complication of other health problems he encountered early in life. Last December, when he was 17 months old, he was classified as a Status 1 patient. From December through April, Justin was "re-extended" as a Status 1 patient seventeen times; although these high-priority patients supposedly receive a transplant in two to six days, Justin spent 133 days as a Status 1 candidate. He died two months ago, still waiting for a liver—and we know that during his wait, less-critically ill patients received livers instead of Justin because they waited closer to a donor.

We all know that patients must wait for organs, in part, because demand exceeds supply. But this scarcity demands that we develop allocation policies that ensure the fair and efficient distribution of organs to patients whose lives depend on a transplant.

To be clear, I support the Secretary's regulations. These regulations are a positive step towards ensuring that all patients, regardless of where they live, have the best possible chance of getting the care they need and deserve. The Department of Health and Human Services has struck an appropriate balance between governmental leadership and the transplant community's technical expertise. The regulations articulate broad performance goals and empower UNOS to establish the specific policies and medical criteria necessary to achieve these goals. If UNOS meets these goals—developing standard criteria for listing patients and determining medical status, as well as creating allocation policies that give priority to the most urgent medical needs—we will have made enormous progress towards a more equitable allocation system.

We can and must improve the availability and accessibility of transplant services for all Americans—and these regulations establish the firm foundation we need to achieve these goals. Thank you.

PREPARED STATEMENT OF REPRESENTATIVE RON KLINK

I applaud the new regulation to fix the problems with the current system for organ sharing and urge the members of this committee to let it be implemented because it will save lives.

Regrettably, there has been more misinformation than information about what this regulation actually says. Let me outline why I think it should be implemented immediately.

Organ sharing is a matter of life and death. The problem is that every year people die unnecessarily because the current organ allocation system is broken. We can do better and I urge you to not let parochial interests get in the way of fixing the problem.

Whether or not you get the organ that will save your life should not depend on where you live. Organs do not and should not belong to any geographical or political entity. But, under the current system, depending on where the organ was harvested, it could be given to someone with years to live—while someone in the next town across the wrong border may die waiting for a transplant.

The most difficult organ to transplant is the liver. Pioneered at the University of Pittsburgh, upwards of 90 percent of all the liver transplant surgeons today were either trained at Pittsburgh or by doctors who were trained there. Yet facilities like Pittsburgh, Mt. Sinai, Cedars-Sinai, and Stanford and other highly regarded transplant centers which take on the most difficult and riskiest transplant patients are struggling with the longest waiting times in the country.

While these centers are highly regarded, many of their patients do not come to them because of their reputations. The fact is that many of their patients only seek them out after having been turned down by their local transplant centers. There is strong evidence to suggest that many smaller transplant centers avoid the riskier transplants on the sicker patients because they are more difficult and would adversely impact their reputations should they not be successful.

Currently there are patients from at least 31 states awaiting organs at the University of Pittsburgh, all of whom are dependent on an organ becoming available in Western Pennsylvania or West Virginia. Is it any wonder that our waiting lists are longer than almost anywhere else in the country. Obviously, this is not an issue that impacts people in one particular geographical region, but it affects everyone

who is waiting for an organ no matter what state or congressional district they come from.

This isn't right. Whether you live or die should not depend on where you live.

This debate is not about pitting big transplant centers against small ones, or about pitting one region against another. It is about making sure that the gift of life goes to the person who needs it the most rather than someone who happens to have the good fortune to live in the right state, county, or city. It's about helping at least 300 people each year to continue to live.

The fact is that the current system discriminates against people who live near the highly regarded centers with the longer waiting lists. It's not their fault that their local center is willing to take the harder and sicker patients when other centers avoid the sicker patients in favor of patients who may be still able to work, go to school, or even play golf while patients elsewhere are near death without any opportunity to receive that organ because they have the misfortune of being on the wrong side of the Pennsylvania-Ohio line.

The worst thing about this whole debate is that the organization that is under contract with the Department of Health and Human Services (HHS) to run the national organ procurement transplant network, the United Network for Organ Sharing (UNOS), is the biggest opponent of any change. Sadly, UNOS is spending upwards of \$1 million of patient fees to lobby against HHS making the system more fair.

All HHS wants to do is: (1) require UNOS to develop policies that would standardize its criteria for listing patients and for determining their medical status, and (2) ensure that medical urgency, not geography, is the main determinant for allocating organs.

HHS should be allowed to proceed. The longer we delay the more lives are at risk. In this day of modern air travel and communications there is no good reason for an organ to stop at the border. There is no good reason why if I passed away while attending the Superbowl in New Orleans that my liver should go to a golfer in Louisiana when I may have a loved one who is in desperate need of a transplant at home.

People are dying because they happen to live in the wrong ZIP Code and because States do not want to share their organs. Nowhere else in society would we allow a monopoly like this to continue. We must put an end to this craziness. There is no room in this country for politics to affect who lives and who dies. The patients who need the organs the most should get them. Period.

OPENING REMARKS OF SENATOR RICK SANTORUM

Senator SPECTER. We have my distinguished colleague, Senator Santorum here. And I thank you for promptness, Senator Santorum, and the floor is yours.

Senator SANTORUM. I thank you, my dear colleague from Pennsylvania, and congratulate you on holding this hearing on what I think is really one of the most important issues that we can deal with here, an issue of life and death and an issue that we have to deal with. It is under our purview.

We set out the statute in the first place as to how this allocation system would work, we have taken on that responsibility, and now we have to, I think, carry forward in making sure that the public trust is kept.

I would just say, the reason we are having the hearing and the reason that these regulations are necessary is simply because of one simple fact, we do not have enough organs that are being donated.

And so anything that this subcommittee can do and the Congress can do to further publicize the need for organ donation, to encourage organ donation, to make it a much more acceptable practice I think is very, very important. And I would commend to you and to your staff whatever has been done on States levels.

I know lots of States have done some things. I am an organ donor. I have a Pennsylvania driver's license. Right under my pic-

ture there, it says organ donor. We do that in Pennsylvania. I know other States have done it.

It is important that we continue to try to publicize as much as possible the need for organs and make it politically desirable, politically correct, if you will, or politically incorrect not to be an organ donor. And to the extent——

Senator SPECTER. We are joined by the distinguished Secretary of Health and Human Services.

Madame Secretary, if you would come up and sit next to Senator Santorum, we welcome you here.

Senator SANTORUM. That is the first issue. Second, as the Senator from Pennsylvania knows, Pennsylvania has 14 transplant hospitals. It is not an easy issue for us in Pennsylvania. There are large centers and there are small hospitals that do this, and they are on both sides of this issue.

So I come to this not as someone who is trying to represent a parochial interest in Pennsylvania, but someone who is trying to do what I believe is best for patients. And I believe what is best for patients is to allocate organs to the patients who can best utilize those organs, who are in the greatest need, irrespective of where they live.

I can tell you, as I said, I am an organ donor. And when I die, I do not care if my organs go to people in Pittsburgh or they go to people in Pennsylvania. I hope they go to someone who can use them best, who needs them the most.

And I think that is the way most Americans feel, and I think that is the way most organ donors feel. I think to have a different kind of approach—frankly, I know several States have taken the position—and Louisiana is one of them, and I know Mr. Livingston is from Louisiana and he is representing the views, at least, of his States legislature and Governor. But the idea of States protections is as parochial and as distasteful an action as I can possibly think. If in fact they really cared about the people in Louisiana or States like Wisconsin or others who have done so, or States like New Jersey that are considering them, then they should pass a law that says that organs should go to people who are Louisiana residents.

But they do not do that. They pass a law that says an organ has to stay within the States, whether the recipient is a Louisiana resident or not.

If you look at the State of New Jersey, two-thirds of the people in New Jersey who have organ transplants do not have them in New Jersey. Yet if they pass a law that says they have to keep the organs in New Jersey, two-thirds of the people in New Jersey who get organ transplants will not get organs from their own States, because they are having most of these done in New York and Pennsylvania.

So if these are truly humanitarian efforts on the parts of the States to take care of people within their borders, then they would have very different laws. But the laws are passed to protect economic interests within their States. And let us be very clear about it. They protect hospitals and doctors and practices for those particular reasons, for economic purposes.

We should not be allocating organs for economic purposes. We should do it because we care about the lives of patients who are in need of these organs.

The final point I would like to make is, there is a lot of debate, and will be a lot of debate, over the next several weeks on a bill that I know the Secretary and I disagree on, on the issue of HMO's. We need to maximize patient choice and quality and access. And a lot will be made as to all these restrictions on people being able to choose their doctor or go and get the procedure they need.

And yet the very same people who argue against the HMO's and against the procedures they use will argue that we should limit people's choices of what hospital they go to to get the transplant that they believe they need from the people who they think are the best to do it.

I come from Pittsburgh, where the waiting time is 800 days, 800 days, well over twice the national average. To limit people's choices of what center they go to, where they believe their best chance of survival is, to limit their choices, because of the limitation on the organs going to that center, is arguing against everything that they argue for in their HMO protection bill.

So if they are going to argue patient choice, patient quality, patient access, then be consistent when it comes to the area of transplants. And they are not. And I hope that this committee and the Senate will resist the efforts to place a moratorium on these regulations.

They are sound regulations. They are balanced regulations. And they are first and foremost on behalf of the patients and the patients' interests in this country.

Thank you.

DIVISION OF OPINION

Senator SPECTER. Thank you very much, Senator Santorum. You accurately state the division of opinion in your State, my State, Pennsylvania, where we have hospitals and constituents on both sides of this issue. And I concur with your views and the views of the secretary, that this ought to be a medical decision and not one governed by economics or regionalism.

SUMMARY STATEMENT OF HON. DONNA SHALALA

Senator SPECTER. Well, we are pleased to have the distinguished Secretary of Health and Human Services, Secretary Shalala, to testify on this issue. This is a matter that the Secretary and I have discussed on a number of occasions. And what we need to do now is to focus the considerations and the arguments to see if we cannot come to a conclusion, proper conclusion, with our colleagues on the House side.

And we welcome you here, Madam Secretary.

Secretary SHALALA. Thank you very much, Senator Specter, Mr. Chairman.

And let me associate myself with Senator Santorum's comments about this rule. I appreciate having the opportunity to be here today. As the leadership of our authorizing and Appropriations Committee requested, we have worked very hard to clarify the goals and the responsibilities of both the department, as well as

the transplant community and understand what responsibilities that the Congress of the United States gave us.

We believe that it is essential that we now go forward so that the doctors and the patients in the transplant community can establish equitable policies that are based on sound medical criteria. And I think that is the point of the rule that the Department has put forward, that these decisions ought to be in the hands of doctors and patients.

I do not think I have ever testified on a subject so suggestive of lessons from biblical teaching or mythology, lessons that tell how humanity is given a great gift and learns to use that gift wisely for the benefit of all or loses the gift when jealousy and self-dealing replace equity and fairness.

In the case of the gift of life provided by organ transplantation, the lessons of the Bible are indeed important. We are witnessing States trying to withhold organs from other States. We are seeing transplant centers hiring lobbyists to influence Federal policy as part of a competition for scarce organs. Patients are pitted against patients.

I remind you that self-interest, exemplified by buying and selling of organs, is what led the Congress to the passage of the National Organ Transplant Act in the first place. The act now requires the Organ Procurement and Transplant Network [OPTN], to assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients.

The network's primary goal is to make sure that Americans who need an organ have an equal opportunity to receive one, consistent with sound medical judgment and without regard to who they are or where they are listed.

I emphasize this last point, because, as I will explain in a moment, I have a deep concern that people are dying in this country not because they lacked health insurance or access to care, but simply because of where they list.

We believe that medical necessity, not geography, should be the No. 1 criterion for who receives organs for transplantation. And we believe that most Americans would be shocked to find out that under our current system, if they or a loved one needs a transplant, that they could lose out to a less sick patient just across the State line.

Patients in some parts of the country can wait as much as five times longer than patients in other parts of the country who have the same severity of illness. Less ill patients receive transplants, while more severely ill patients, perhaps only a few miles away, die.

We need a level playing field so that the same medical criteria are used for all patients, so that organs are allocated according to medical need. And that is why we issued our April 2 rule.

It calls on the OPTN and our contractor, the United Network for Organ Sharing [UNOS], which operates the network, to develop allocation policies that will reduce these inequities. That is, we called on them to design the allocation policies.

Let me repeat that. The April 2 rule contains no allocation policy. It calls on UNOS to develop a policy that will bring this fragmented and irrational system to an end.

The rule contains three common sense approaches for improving fairness and relying on medical criteria for allocating organs. First, the criteria for placing patients on waiting lists are to be standardized and based on objective medical criteria. UNOS actually agrees with this goal.

Second, the criteria for determining the medical status of patients are to be standardized and based on objective criteria. Again, UNOS agrees.

Third, medical urgency is to be main criterion for allocating organs, and organs are not to be confined to the artificial geographical areas that have no medical rationale.

As you know, the April 2 patient fairness rule has been controversial. An earlier appropriations bill delayed the implementation of the rule until October 1. Subsequently, in addition to suspending the organ donation rule, the House Appropriations Committee also included language in the fiscal 1995 appropriations bill to delay our patient fairness regulation by another year.

I deeply respect the views of those in Congress who seek to delay the patient fairness rule. And I believe they have the best interests of patients at heart. However, I am deeply concerned that opposition to the rule is based on misinformation generated by political lobbying by UNOS that has mischaracterized the Department's intent and the meaning of the patient fairness regulation.

So we appreciate the opportunity to set the record straight. And if I might shorten my testimony, Senator, let me simply go through a series of claims and finish my summary.

First, UNOS has claimed that the rule creates a single national waiting list that would result in more deaths and longer waits for patients across the country. This is false. The rule asks UNOS to develop the allocation policy and does not require a national waiting list. What the rule calls for is fairness. And it emphasizes medical criteria over nonmedical criteria.

UNOS claims that the rule will force doctors to transplant livers into the very sickest patients, contrary to sound medical judgment. Again, this is not true. Our regulation explicitly says the opposite. We believe that transplants should be performed on the basis of medical urgency, consistent with sound medical judgment. We specifically direct that allocation policies should not require transplantation in futile cases and should not waste organs.

UNOS claims that the rule will force transplant centers to close. This, too, is false. If anything, a fairer distribution of organs should enhance the ability of all centers to have better access to matching organs.

UNOS claims that the organ procurement areas with excellent donation rates will lose organs to areas with poorer donation rates. Once again, false. Already 33 percent of donated organs are used outside the local area. And broader sharing will mean patients will benefit from a wider pool of organs.

UNOS has even gone so far as to claim that the Federal Government should have no voice in these issues. That is simply nonsensical. The transplant network is operated on a day-to-day basis by a private sector organ network. Our regulation protects that structure.

But the law also demands that the organ network be accountable. And my Department has a clear responsibility to ensure the purposes of the act are carried out. And keep in mind that Medicare alone pays for 50 percent of the transplants performed in this country.

During the past several months, the HHS staff and UNOS representatives began a series of discussions about transplant policies and the meaning of the rule. During these lengthy discussions, we clarified several issues that had been most concerned to UNOS.

At several points, it appeared that there was broad agreement between the two parties on the clarifications made by our staff. At one point, they removed their legislative action kit from its Internet site, although UNOS would not publicly correct the misinformation that had been spread throughout the transplant community and the Congress.

I understand that at the last meeting between HHS and UNOS the respective parties in the room concurred on draft language that both sides felt could form the basis for a mutual understanding. In the end, though, they would not agree to that language.

UNOS has informed HHS that it will not correct the record unless the Department agrees in advance to change the regulation. It is the UNOS record, I believe, that has resulted in widespread misunderstanding of the patient fairness rule. Members of this subcommittee have expressed reservations about the April 2 rule. I have taken these concerns seriously.

I also know that Members of Congress are fair and want a debate that is based on facts and what is best for patients. I appreciate the tough questions that Members have asked and the examination of the regulation from every angle.

We purposely delayed the implementation of the rule so that there would be time for additional comment and for Congress to hold hearings on these issues. And as I said earlier, we have worked hard to clarify the scope and intent of the rule. And I believe that any further delay would be counterproductive.

PREPARED STATEMENT

I hope that you will conclude, as I have, that the April 2 rule is our best chance of meeting the goals of the National Organ Transplant Act and of protecting patients.

Thanks for the opportunity to set the record straight.

Senator SPECTER. Thank you very much, Madam Secretary.

[The statement follows:]

PREPARED STATEMENT OF HON. DONNA SHALALA

Chairman Specter, Senator Harkin, distinguished members of the Subcommittee, I appreciate having the opportunity to be here today to testify about our regulatory guideline designed to ensure a fair organ transplantation network for patients. At the request of you and Chairman Livingston, and the leadership of our authorizing committees, we have worked hard to clarify the goals and responsibilities of both HHS and the transplant community. We believe it is essential that we now go forward so that doctors and patients in the transplant community can establish equitable policies that are based on sound medical criteria.

Mr. Chairman, without a doubt, organ transplantation is one of the wondrous medical developments of the century. Organ transplant surgery has given life where death was once a certainty for tens of thousands of chronically ill Americans. Every

patient who survives transplant surgery to lead a productive life has been touched by a miracle.

I also want to reiterate our strong commitment to increasing organ donations, in particular the regulation we issued earlier this year to strengthen hospital participation in the organ procurement process.

But like all miracles, these are in short supply. Every day, eleven Americans whose lives could be saved by transplantation die because there are not enough organs for everyone who needs them. Increasing organ donation rates must be our number one priority.

Unfortunately, only 5,500 cadaveric donors, about one half to one third of all potential donors, contribute organs for transplantation. While the number of cadaveric organ donors has increased by 30 percent, the number of deaths on the waiting lists has also grown, by nearly 177 percent.

Last December, the Department of Health and Human Services announced a nationwide initiative to increase organ donations. A national partnership of public, private and volunteer organizations is working together to identify and overcome known barriers to organ donation. The centerpiece of the initiative is a new regulation, which took effect August 21, that we believe will increase organ donation by 20 percent within two years. This regulation requires hospitals participating in Medicare or Medicaid to report all deaths to organ procurement organizations so that medically suitable donors can be more readily identified. The rule is based on the effective Pennsylvania state law that requires the reporting of deaths to state organ procurement organizations.

Regrettably, the House fiscal year 1999 Labor-HHS-Education appropriations bill was amended with language that would suspend implementation of this important rule. We hope members of both Houses will agree to omit this language from the final bill. This proposal, which has strong support from doctors and patients in the transplant community, could save thousands of lives.

Increasing organ donation is our most important transplant policy goal, but not the only one. We also must do a much better job of meeting the central mandate of the National Organ Transplant Act: to ensure an equitable nationwide system for the distribution of transplantable organs. Under existing policies, where a patient lives and which transplant hospital a patient chooses are often the primary determinants of whether the patient receives an organ. In other words, where you live and where you list can determine whether you live or die.

Medical urgency—how badly a patient needs the transplant and his or her chances of survival—is not always the main factor in deciding who lives and who dies. I believe that the emphasis on geography instead of medical judgment is the reason that patients in one part of the country wait as much as five times longer than patients in other parts of the country who have the same severity of illness. Policies of the Organ Procurement and Transplantation Network should be based on medical criteria, as developed by the transplant community itself.

Non-medical criteria, such as geography, should not drive allocation decisions. A person's wealth should not drive allocation decisions. A patient's celebrity should not drive allocation decisions. Politics should not drive allocation decisions. We want allocation decisions to be based on medical criteria.

Allocating scarce organs to patients on the basis of geography is fundamentally unfair. Not only is current allocation policy inequitable, existing allocation boundaries simply do not make sense. The transplant network is using boundaries that were designed for organ procurement. These boundaries are not based on medical criteria and I believe it would be a mistake to continue using them for allocation purposes.

Transplant centers have adapted to the current system, and in fact, have proliferated under it. But patients have not. Regardless of any economic gains for local transplant centers, the system is bad for patients. Improving the system for patients is the reason the Department issued a regulation April 2 that asks the Organ Procurement and Transplantation Network to develop fairer policies that are based on medical criteria.

As you know, the April 2 patient fairness rule has been controversial. An earlier appropriations rider delayed implementation of the rule until October 1. Subsequently, in addition to suspending the organ donation rule, the House Appropriations Committee also included language in the fiscal year 1999 appropriations bill to delay our patient fairness regulation by another year.

I respect the views of those in Congress who seek to delay the patient fairness rule, and I believe they have the best interests of patients at heart. However, I am concerned that opposition to the rule is based on misinformation generated by a political lobbying campaign that has mischaracterized the Department's intent and the meaning of the patient fairness regulation.

In 1991, the HHS Inspector General found that the national Organ Procurement and Transplantation network was inequitable, particularly with respect to race and geography, and that it did not meet the intent of the 1984 Act. Earlier this year, a House panel examining this issue asked the Inspector General to update its findings. The Inspector General issued its updated report in June, which found that the inequities identified in 1991 remain in the network, and in some cases have worsened, particularly for African Americans. Let me read you the conclusion reached by the Inspector General two months ago:

Our brief review of these data lead us to reaffirm the importance of the central message we presented in our 1991 report—that the national organ allocation system should focus on equity among patients, not among transplant centers, and on common medical criteria, not the circumstances of a patient's residence or transplant center affiliation. We continue to believe that the April 2, 1998 HHS rule moves in that direction.

Under the current policy, patients who are less ill receive transplants while more severely ill patients, perhaps only a few miles away, die. We all have friends and relatives who live in different parts of the country. Should any one of them have a better chance of living than the other if they needed an organ transplant? Is it fair that patients with virtually identical medical needs are treated differently solely because of where they live?

The unfairness exists, not only between different parts of the country, but even within states. For example, the median waiting times for the two major liver transplant centers in the State of Kentucky are vastly different. One recent report found that the median waiting times for livers at one of the centers was 38 days while it was 226 days at another. In Louisiana, the median waiting time at one center was 18 days, while it was 262 days at a different center. In Michigan, one center had a waiting time of 161 days while another major center in the State had a waiting time of 401 days. And so it goes across the country, inequity within states, and unfairness from one state to another.

These waiting list disparities are the most visible shortcoming of the current system. Less visible are the resulting inequities among those who receive organs. Where waiting times are the shortest, organs may go to patients who are less ill; while at the same moment, in areas where patients wait longer, organs often are not offered to patients with greater medical need. In the worst cases, patients die in areas where waiting times are long, while, at the same time, organs are being made available to patients who are less ill in areas with shorter waiting times.

The April 2 rule does not impose an allocation policy. Instead, it calls on the contractor that administers the network, the United Network for Organ Sharing, or UNOS, to develop an allocation policy that will reduce current inequities in the network. I want to be clear about this, because there appears to be misunderstanding about the rule. The April 2 rule contains no allocation policy. It calls on UNOS to develop the policy. The rule is consistent with the Department's long-standing position that the development of any policies requiring medical judgment be left to the transplant community. We will rely on the judgment of transplant professionals to establish policy reforms. And they will have broad latitude to develop policy within the parameters of the regulation.

The rule contains three common sense goals that are consistent with the equity requirements of the National Organ Transplant Act. The first goal requires that criteria for placing patients on waiting lists be standardized and be based as much as possible on objective medical criteria. The network cannot be truly fair if the standards for placing patients on waiting lists differ across the country. UNOS agrees with this goal and is working toward it.

The second goal requires that criteria for determining the medical status of patients be standardized, again on the basis of objective criteria. Uniform criteria for determining medical status will prevent gaming of the system. UNOS also agrees with this goal and is working toward its accomplishment.

The third goal requires that medical urgency, not geography, be the main criterion—not the sole criterion—for allocating organs. This goal also meets the intent of the Organ Transplant Act for an equitable nationwide organ transplant network. UNOS objects to this goal, and if their position prevails, the current inequitable system will be maintained.

There is a central purpose to the performance goals, which is to ensure, to the maximum extent possible, that all patients, regardless of where they live, are treated the same. Because there are not yet enough organs to save everyone on the waiting lists, I believe we must, at a minimum, guarantee fairness, while we continue to strive to increase donation.

I recognize that there are legitimate diverse views in the transplant community about the third performance goal, which requires reform of allocation policies. Small

transplant centers worry they will be swallowed by large transplant centers. Organ Procurement Organizations that have worked hard to obtain transplantable organs are concerned that organs will flow from their state, leaving a shortage. Such concerns must be debated by the transplant community and they should strive to reach consensus on the best policies for patients.

Unfortunately, to this point, UNOS has failed to seize the opportunity offered by the rule to develop consensus about policy improvements. In fact, UNOS has gone to great lengths to preserve the current unfair system. It has launched a political lobbying campaign against the April 2 rule. This campaign has been characterized by misinformation. The essence of the UNOS campaign has been to create phantom policies and use scare tactics that have hospital administrators and patients around the country up in arms. UNOS has made available form letters, part of a self-described "legislative action kit," to surgeons and patients across the country.

I am deeply concerned about these efforts to misrepresent the provisions of the regulation. I have received numerous letters from Members of Congress, transplant professionals, patients, and the public that reflect inaccuracies published by UNOS. I am especially distressed that UNOS is needlessly frightening transplant patients.

UNOS has claimed that the rule creates a single national waiting list for patients that would result in more patients' deaths and longer waits for all patients across the country. This claim is completely false. As I have said, the rule asks UNOS to develop the allocation policy. There is no requirement for a national waiting list anywhere in the rule. The rule calls for fairness. How the fairness is achieved in terms of allocation policy is primarily up to UNOS. Leading members of the transplant community have presented proposals to UNOS to remedy the current system's unfairness with very little, if any, adverse impact on local transplant centers. There have been several experiments in allocation policies involving broader sharing of organs that have been sanctified by UNOS. These experiments are interesting and worthy of consideration. But instead of consideration, UNOS has resorted to frightening patients and surgeons. The scare tactic of the national waiting list is a central theme of the phantom policy created by UNOS.

I reiterate that the Department does not have a preconceived notion of any allocation policies. We are relying on the transplant community to develop the policy. Any policy that is sensible, is based on sound medical judgment, and reduces geographic inequity, will be taken seriously by the Department.

UNOS has claimed that the rule will force doctors to transplant livers into the very sickest patients, contrary to sound medical judgment. This claim also is false. We know that transplanting the very sickest patient is not always the best course. We believe that transplants should be performed on the basis of medical urgency, the definition of which includes viability and chances of survival. Further, it is up to UNOS to develop policies on medical urgency.

UNOS claims the rule will force transplant centers to close. There is nothing in the regulation that would force any centers to close. On the contrary, a fairer distribution of organs should enhance the ability of all centers to have better access to matching organs for transplantation.

UNOS has claimed that organ procurement areas with excellent donation rates will lose organs to areas with poorer donation records. This is another false assertion. Already, over 35 percent of donated organs are used outside the local area. Our organ donation initiative should result in increased organs for every procurement area. Also, broader sharing will mean that patients will benefit from a wider pool from which to draw.

I think the most outrageous UNOS claim is that the regulation would hurt minorities and the poor. In the first place, the current system is not fair to minorities, as the Inspector General has reported. Minorities can only benefit from the fairer policies the regulation attempts to encourage. As for UNOS claims about the poor, the truth is that Americans who cannot afford to pay for transplant surgery do not even get on the waiting list. So the opposite of UNOS's allegation is true: it is the current unfair system that has negative consequences for minorities and the poor. We are trying to change the system. UNOS is trying to preserve it.

Finally, I would like to comment on the UNOS claim that the Department lacks the authority to issue any rules governing the Organ Procurement and Transplantation Network. As I have said, the National Organ Transplant Act gives the Department the authority to oversee the network. The primary reason the Act was passed in the first place was because the unregulated network was rife with abuses. Also, the Department, through Medicare and Medicaid, pays for more than half the transplant surgeries in the United States. We pay for most of the listing fees charged by UNOS. To say we have no basis to issue regulations when our authority is clear is a disservice to Congress, which created the network, and to the patients, whose transplant bills we pay.

I regret that UNOS has frightened patients and perhaps jeopardized organ donation in some areas of the country. Only a year ago, a former President of UNOS, Dr. James Burdick, warned against such scare tactics. Dr. Burdick sent a statement to all UNOS members. It said:

“* * * the community must generally understand the likely impact of a new or revised policy. In recent months, there have been conflicting accounts in the news media of the potential effects of revisions to liver allocation policy. While diverse views are held within the community, we must realize that contradictory or inaccurate statements about the policy’s effect can needlessly confuse or frighten those with the most at stake—patients desperately awaiting transplants.”

What has been the response to Dr. Burdick’s warning? There have been charges that the April 2 rule will kill people. There have been charges that the April 2 regulation discriminates against minorities. There have been charges that patients will have to travel great distances for transplants. There have been charges that transplant centers will be shut down. All these charges come from UNOS and all of them are false. Dr. Burdick’s responsible policy was flatly rejected.

On June 18, the Senate Labor and Human Resources Committee and the House Commerce Committee conducted a joint hearing about the April 2 patient fairness rule. Members of the Committees urged HHS and UNOS to put aside their differences and work out a mutual understanding of policy that would benefit patients. We agreed with the Members. Beginning the very next day, HHS and UNOS began a series of discussions about transplant policies and the meaning of the rule. The Administrative Procedures Act prevented any actual negotiation about the regulation. Any changes in the rule, if necessary, will result from the public comment process, and UNOS has offered comments as part of that process that we will seriously consider.

During the lengthy discussions with UNOS, HHS staff clarified several issues that had been of most concern to UNOS: specifically, allocation policies will be developed by UNOS, not the Department. HHS emphasized that the regulation does not require a national list, and that it would be up to UNOS to develop an allocation policy that results in broader sharing. The key goals for any policy developed by UNOS must be to benefit patients and improve the current system.

HHS reiterated that there should not be an arbitrary policy requiring that only the sickest patients be transplanted, but that the patients with the greatest medical urgency, based on sound medical judgment, not geography, should be transplanted. HHS made it clear to UNOS that it should not develop policies that adversely affect small transplant centers or unduly benefit large transplant centers.

In fact, HHS would reject any policies that would result in the wastage of organs.

At several points in these lengthy discussions, it appeared that there was broad agreement between the two parties on the clarifications made by HHS staff. At one point, UNOS removed its legislative action kit from its Internet site, although it would not publicly correct the misinformation that had been spread throughout the transplant community and the Congress. I understand that at the last meeting between HHS and UNOS, the respective parties in the room concurred on draft language that both sides felt could form the basis for a mutual understanding. In the end, UNOS would not agree to the language. It seems that UNOS believes its political interests are best served by suspension of the patient fairness regulation and continuation of the current system. UNOS has informed HHS that it will not correct the record unless the Department agrees in advance to change the regulation. It is the UNOS record, I believe, that has resulted in widespread misunderstanding of the patient fairness rule.

Many of Members of Congress have expressed reservations about the April 2 rule. I know their concerns are sincere and I take them very seriously. I want to respond to every one of them. I know that you are fair and agree that the debate should be based on facts and what is best for patients.

My fervent hope is that the polarization created by the UNOS lobbying campaign is the result of a misunderstanding of the rule and its intent. I say this because I believe that all of us—the Department, UNOS, and Members of Congress, want what is best for patients.

I want you to ask me the tough questions and examine the regulation from every angle. One of the reasons we initially delayed the implementation of the rule ourselves, prior to the action by Congress, is so that there would be time for additional public comment as well the opportunity for Congress to have hearings on these issues. As I said earlier, we have worked hard to clarify the scope and intent of the rule and believe that any further delay would be counterproductive. I am hopeful that you will conclude, as I do, that the April 2 rule is our best chance of meeting the goals of the National Organ Transplant Act.

Thank you for the opportunity to testify and set the record straight. I will be happy to answer any questions that you may have.

REMARKS OF SENATOR ROBERT TORRICELLI

Senator SPECTER. Senator Torricelli has arrived. And if you would wait, Madam Secretary—

Secretary SHALALA. I would be happy to.

Senator SPECTER. Questions are going to be limited. As I said at the outset, we are going to have to conclude the hearing by 11 o'clock. But I think it would be useful to have Senator Torricelli's views, which I think are in opposition to your position. And we can then perhaps have a brief three-way discussion.

Secretary SHALALA. They are, but I should note that we are good friends.

Senator SPECTER. Well, I am sure that will prevail, notwithstanding the discussions.

Welcome, Senator Torricelli.

Senator TORRICELLI. Thank you, Mr. Chairman, very much, and Madam Secretary.

Senator SPECTER. The floor is yours under the 5-minute time rule.

Senator TORRICELLI. Thank you very much for the opportunity.

Mr. Chairman, with much being said today about our national organ transplantation program in our various States, this much should be clear to all of us: This program has been an extraordinary success. In 15 years over 200,000 Americans have received an organ.

Not only is the technology working, there are people who are living and breathing as a result of the cooperation and the generous gifts of those in the last moments of their life. The problem that remains is simply that not enough Americans are donating their organs. Less than 1 percent of deaths result in organ donation with 4,000 Americans dying every year, waiting for an organ donation.

This is the problem, not the fact that the individual States have initiated their own systems for distributing the organs. The new HHS proposal may be well intentioned, but I, along with 26 of our colleagues in the Senate, are concerned that by removing geographic criteria, the proposal will not improve overall levels of donation and transplantation, but will rather shift donations and transplantations along different regions of the country and impose great new costs.

Our belief is that under this scenario the number of actual donations and transplants will not increase. We will only have new burdens.

Transplant programs across the Nation including those in States represented by members of this subcommittee. Wisconsin, South and North Carolina, Washington, and Missouri have repeated the warning that centralizing the system will shift organs away from local facilities.

As organs begin to flow to large transplant centers, these community-based centers will be forced to close, because they will be unable to maintain the volume necessary to operate. The consequences will be felt most greatly among our nation's most dis-

advantaged patients, the poor and minorities, many of whom will be unable to bear the expense of travel.

Over 23 percent of the transplant patients nationwide rely on Medicaid, which does not provide coverage for travel expenses. In addition, I fear that large centers may refuse to serve uninsured patients, many of whom are minorities, because of the increased pool of insured patients for them to pick from. A recent study of the largest transplant centers indicated that only 7 percent of liver transplant patients were minorities, which is 23 percent nationally.

In my State, we are very proud of our locally based organ donation system. A citizen of New Jersey waits only 26 days for a liver transplant. We have an active system to encourage our citizens to donate their organs. We maintain a list, and it has resulted in one of the lowest, or the lowest, waiting periods in the Nation.

A citizen of the United States can be expected to wait 250 days, on average if they live in other States. That is not because our State is not meeting its responsibility or many other States. The answer is not to nationalize the system and destroy a system that is working. The answer is for other States to do what we have done.

Our fear is that the smaller centers that now exist in our State will not be able to compete and will no longer exist if this system is nationalized. Not only have we reduced the waiting period in New Jersey with what is a model program, but we have ensured that based on race and income that no one is disadvantaged.

Fully one-third of the people receiving transplants in our State do not even have private health insurance, but they are protected. Under the system being proposed in nationalizing this process, the question arises: How will the poor be protected? How will they travel hundreds or even thousands of miles with their families, wait for transplants and bear those costs?

PREPARED STATEMENT

That is the risk of nationalizing a system and ending the state-wide systems, which I believe are working and can be made to work so very well. That, Mr. Chairman, I believe is the reason why the House of Representatives appears on the verge of imposing a year wait before nationalizing a system and why 26 of our colleagues, including 4 members of this subcommittee, have joined in my legislation for a 1-year moratorium to ensure that we understand the consequences on the poor, on the uninsured, on waiting periods and what it would mean to compromise or end these various State systems, which we believe are working so well.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ROBERT G. TORRICELLI

Thank you Chairman Specter for holding this hearing and for the opportunity to testify. The issue of the proposed HHS organ donation regulations and its impact on our organ donation and allocation system is one of the most pressing before Congress.

This debate has re-focused national attention on our organ donation system. Among the great successes of the last decade has been the successful development of community-based systems of organ donation. In the last 15 years, nearly 200,000 Americans have received an organ. Last year alone, 20,000 Americans received a donated organ.

Notwithstanding this success, the program is still struggling to provide organs for all those who need them. With organs being donated in less than one percent of deaths, 4,000 Americans die every year waiting for organs in the U.S. Today, tens of thousands of names wait for new organs on Regional and State lists for new organs and a new name is added every 16 minutes.

Clearly we must improve the current system to encourage more individuals to donate and to facilitate the accessibility of donated organs to those in need. However, while the new HHS proposal is well-intentioned, I am concerned that by removing geographic criteria, the proposal will not improve overall levels of donation and transplantation but rather will shift donations and transplantations among different regions of the country.

Under this scenario, the number of actual donations and transplants will not increase. The only thing that will change is who receives and who performs the donations. Transplant programs across the nation including those in States represented by members of the Subcommittee in Wisconsin, South Carolina, North Carolina, Washington, and Missouri have repeated the warning that centralizing the system will shift donated organs away from community based facilities to a handful of large transplant centers that have the longest waiting lists.

As organs begin to flow to large transplant centers, many community based centers will be forced to close because they will be unable to maintain the volume necessary to operate. When locally-based transplant centers are closed, patients and their families will be forced to travel to other states at their own financial expense and medical risk.

The consequences of this will be felt most greatly among our nation's most disadvantaged patients, the poor and minorities, many of whom will be unable to bear the expense of travel. Over 23 percent of transplant patients nationwide rely on Medicaid, which does not provide coverage for traveling expenses. In addition, I fear that larger centers may refuse to serve uninsured patients, many of whom are minorities, because of the increased pool of insured patients for them to pick from. A recent study of the nation's largest transplant centers show that, in 1996, only 7 percent of their liver transplant patients were minorities versus 23 percent nationally.

In my State, we are proud of our locally based organ donation system. It actively promotes organ donation within our communities and serves the sickest patients first, close to their homes. It has resulted in shorter waiting periods, increased donations, and healthier patients. A person in New Jersey need wait only 26 days on average for an organ, compared to a 250-day national waiting period.

Our system also ensures that all of our citizens, including the poor, will be accommodated. Fully 30 percent of patients in New Jersey have no access to private insurance, but, through our system of charity care, we're insuring that regardless of income, people can receive donations.

Mr. Chairman, the potential consequences of the HHS proposal on local centers and their patients are too great for us to act in haste. I understand that for several months, HHS and the United Network of Organ Sharing (UNOS) have been in confidential discussions to address the concerns raised by many members of Congress and the transplant community. However, the October 1 deadline is rapidly approaching. It would be tragic if we were to allow a lack of time to prevent a successful culmination to these efforts.

As I am sure the Chairman knows, I have introduced legislation that now has 25 bi-partisan cosponsors, including several members of this Subcommittee that would delay for one year the regulations while HHS conducts a study to determine their impact. I am confident that with greater time to consult with the medical community, particularly those serving low-income patients, HHS will be able to develop new regulations that will raise the overall level of organ donation system.

Again, thank you for the opportunity to be here today.

NATIONWIDE DISTRIBUTION OF ORGANS

Senator SPECTER. Senator Torricelli, let me start with a question on a subject raised by the Secretary. And that is, from the existing legislation, which provides assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients.

Does not the articulation of a policy for nationwide distribution of organs equitably among transplant patients really resolve the issue on existing policy?

Senator TORRICELLI. Mr. Chairman, I believe that there is a misconception in our State policies that there is not a national distribution. Forty percent, for example, of the organs donated in New Jersey go into a national pool. There is national distribution. The States simply are allocating them locally first.

But where there are successful statewide programs, there are an abundance of organs that are going to those States that do not have these programs.

Senator SPECTER. Well, that is an interesting answer, Senator, but I do not think you can have it both ways. When you discuss smaller centers and their ability to compete, that is really an effort, as are some of the other efforts, that I understand your point, but that is to protect New Jersey. That is not to have a national system.

And with all respect, it really is not a question of whether centers can compete. It is a question of whether needy people can obtain organs.

Senator TORRICELLI. That is exactly the question. I would not defend a local hospital's interest if it meant that a single citizen would have a better access to organ donation. But I think the facts speak for themselves.

We have a system where the people of our State, and of many other States, including one-half the members of this committee, are meeting their local responsibilities. Our systems are working. Our citizens are getting these transplants. And indeed so successfully that we are able to export almost one-half of the organs donated in our State.

But we are doing it in hospitals where people, including poor people, one-third of them with no insurance, can drive to their local centers, not fly to Chicago, Nebraska, or Pittsburgh. Their families can be——

Senator SPECTER. How about Philadelphia? It is very close. [Laughter.]

Senator TORRICELLI. For Philadelphia, we have a special place in our hearts. [Laughter.]

Senator SPECTER. Be careful on your testimony. You may want to go to Jefferson one day, and this is all recorded. [Laughter.]

Senator TORRICELLI. But, Mr. Chairman, there is a real problem since so many of the people who receive this care are indigent. And as I suggested, in our State 30 percent have no health insurance. And the Federal Government is not providing transportation costs.

The question arises, if a poor person who lives in Newark or any other major city in the country even has an organ donated, how do they deal with the cost of going to Chicago? And how about their families? And how about the long period they have to remain there?

Senator SPECTER. But what reason do you have to assert, as you have on a couple of occasions, with reference to minorities and poor people—and I share your concern there—that they will be treated any worse under a national system?

Senator TORRICELLI. Well, under our——

Senator SPECTER. If you make a determination as to who needs it the most, is that not really the best assurance that there will not

be a determination by who has the ability of pay or who may have a preferential status, not being poor, not being a minority?

Senator TORRICELLI. There is if someone is paying the bills. In our system, under indigent care in our States and in many other States that have these model programs, we ensure that a person who has an organ being donated is treated financially no different, is put in our system of indigent care in our State and the bills are paid.

We are concerned that if our system now is superseded by a national system, that that will no longer be available. And all of a sudden, cost will become a major obstacle to the indigent.

Senator SPECTER. Senator Torricelli, let me raise a legal issue. You are a noted constitutional scholar.

Senator TORRICELLI. Only by you, but thank you for noting that. [Laughter.]

Senator SPECTER. Well, no; I think that "Fox News Sunday" recognized you as a national scholar this week and "Meet the Press" and others, Senator Lautenberg and others.

Is there not a real constitutional issue here about having States enact legislation to limit organs to their home State under the commerce clause and also under the supremacy clause with the Federal policy being that which I just read to you?

Senator TORRICELLI. Well, I will admit to you, Senator, this is my first appearance on behalf of States' rights in my long service in the U.S. Congress. [Laughter.]

It is not a cause of which I usually have sympathy. I do think, however, in the traditional role of the States, both in ensuring health care and providing indigent care and in the regulation of health care industries within our States, which traditionally have had a strong or even a dominant State role, this is not unusual.

But indeed, I would be less troubled if I saw the Federal Government duplicating State by State what we are doing in our individual States than by the program that is being proposed. I do not think we are simply nationalizing what has been a series of State successes. I think we are compromising what has been a series of State successes.

Senator SPECTER. Well, thank you, Senator Torricelli. We have a tough issue here.

Madam Secretary, I am going to give you the last word on the panel. We have a tough, tough matter here. When Senator Torricelli refers to members of this subcommittee, there was no effort made to insert a clause similar to that in the House bill.

So I think that—and in the full committee, as well, that we are satisfied. What we will do on the floor, I do not know. But we have a very tough bill, which we have to get out.

One of the concerns that I have is with so many collateral issues. One of my colleagues said that all the air is going to be sucked out of every room in Washington now that we have the Starr report out. And I think we have to focus on the important work of September, which is the appropriation process.

We have a lot of big matters: The NIH funding, and Head Start, labor safety, et cetera. And I do not want to see us bogged down over riders. And this is a big one. So we are going to have to figure out a way, and I am prepared to work with you, Madam Secretary,

to find the answer here, which does not start another civil war over States' rights.

New Jersey is a little far to the north, but I hear secession.

Secretary SHALALA. Thank you very much, Senator. I would urge Senator Torricelli to look at the inspector general's report on the issue of racial disparities. She has suggested that in fact his description of poor people and minorities being taken care of under the current system is exactly the opposite, that racial disparities have actually increased over the years as this system has evolved, and that a correction of the system is necessary to protect the rights of low-income people and of minorities.

Second, I would simply say to Senator Torricelli that one-half the people in New Jersey now go outside the State to get an organ, that one-half clearly stay in the State. And a fairer system will protect both the people of New Jersey, whether they are rich or poor, as well as the people of Pennsylvania.

Senator SPECTER. All right. Thank you very much. We could go on at some considerable more detail. But as I say, we have to conclude by 11 o'clock.

We thank you very much, Madam Secretary.

And thank you, Senator Torricelli.

Senator SPECTER. We will now call Dr. Bennett, Mr. Irwin, Dr. Miller, Dr. Pfaff. If you would step forward promptly, please.

We had talked about limiting the—if we can have order in the hearing room, so that we can proceed, please.

We had talked about limiting the statements from 5 to 3 minutes. But we will maintain the statements at 5 minutes. But we are going to insist that we stay right on time, because, to repeat, we have to conclude the hearing by 11 o'clock.

**STATEMENT OF RONALD W. BUSUTTIL, M.D., PRESIDENT-ELECT,
AMERICAN SOCIETY OF TRANSPLANT SURGEONS**

Senator SPECTER. We begin with Dr. Busuttil, president-elect of the American Society of Transplant Surgeons and director of the Dumont-UCLA Transplant Center. Welcome, Dr. Busuttil, and the floor is yours.

Dr. BUSUTTIL. Thank you, Senator Specter, and thank the committee for allowing me to make this presentation.

I am Dr. Ronald Busuttil, professor of surgery and chief of the Division of Liver and Pancreas Transplantation at the UCLA School of Medicine. The UCLA liver transplant program is one of the larger programs in the country. In fact, it is the most active transplant program in the world, performing close to 300 liver transplants per year.

I am here today testifying as a transplant surgeon and as president-elect of the American Society of Transplant Surgeons. I will be brief. And I would like to emphasize several key points in my oral testimony today.

First, the two aspects of the proposed rule which surgeons most strongly and uniformly support are standardized listing criteria and standardized criteria for determining the medical status of patients awaiting a transplant. These criteria are already being used by liver transplant programs in the United States.

When I testified before a joint Senate and House hearing on the OPTN rule almost 3 months ago, I suggested that the same criteria used by all transplant centers, coupled with better enforcement, might go a long way toward resolving the concerns of those who have focused on perceived geographic differences and waiting times for the most seriously ill patients awaiting liver transplants.

I also suggested at that time that in fact waiting times had already become relatively equal throughout the country for the most critically ill patients. Today with data for 1998, through the month of August, which is now available, I would like to call the committee's attention to the fact that for status one patients, the most critically ill, the mean waiting time for a transplant across the country is 4 days, with not a great deal of regional variation.

For example, the mean waiting time in my State, California, during this period was 2 days. The mean waiting time in Pennsylvania was 5 days. The mean waiting time in New York was 2 days; in Florida, 3 days; and in Texas, 2 days.

Let me additionally say, as I emphasized in my June 18 testimony, that many of us in the transplant community do not believe that time on the waiting list is necessarily the best indicator of a fair organ allocation system, because there are so many clinical variables that go into determining waiting time.

But even if waiting time were the crux of the issue, I would suggest that the rationale for rushing this rule into effect would seem to have disappeared.

This brings me to my second point. We have for some time now been trying to point out that the Department's apparent determination earlier this year to give priority to sickest patients first without geographic consideration would in fact be detrimental to the goal of providing the most Americans with life-saving transplants.

This policy, which has been modeled for liver transplantation, has actually been shown to have significant disadvantages to alternative systems, including the current one. That is not to say that the current one is the best. And clearly we believe that some modifications are in order.

However, giving priority to sickest first over broad geographic areas would be wasteful and dangerous, resulting in fewer patients transplanted, increased death rates, increased retransplantation due to poor organ function—and I would like to emphasize that point—and increased overall cost of transplantation.

Senator SPECTER. Dr. Busuttil, your yellow light is on, so I am going to ask you to summarize before the red light appears.

Dr. BUSUTTIL. One additional problem with requiring broad geographic transportation of organs is that it would curtail the use of the new split liver technique, in which a single organ is divided to provide transplants for two recipients. And full utilization of this technique will allow an additional 1,000 donors per year.

I would like to make a final point before concluding my oral testimony. When I appeared before Congress on June 18, I made it clear that our Society of Transplant Surgeons was prepared to work as intensively as possible with the Department of Health and Human Services to resolve our concerns.

To date, we have received no indication from them that they wish to address the concerns that we achieved. Based on this—

PREPARED STATEMENT

Senator SPECTER. Dr. Busuttil, your time is up. We are on a very tight time schedule. I am not going to stop you in midsyllable like they do in the Supreme Court to me, but we are going to have to stick within the time.

Dr. BUSUTTIL. I would like to conclude by saying that we urge the committee to block the implementation of this rule as it now stands.

Thank you, and I apologize for going over.

Senator SPECTER. Thank you very much, Dr. Busuttil.

[The statement follows:]

PREPARED STATEMENT OF RONALD W. BUSUTTIL, M.D., PH.D., F.A.C.S.

I am Dr. Ronald Busuttil, Professor of Surgery and Chief of the Division of Liver and Pancreas Transplantation at the UCLA School of Medicine. The UCLA liver transplant program is the most active transplant program in the world, performing close to 300 liver transplants per year.

I am here today as President-elect of the American Society of Transplant Surgeons (ASTS) and as a transplant surgeon representing the transplant programs of the University of California system at Davis, Irvine, Los Angeles, and San Diego, but most importantly as a patient advocate to testify about Final Rule regarding the Organ Procurement and Transplantation Network (OPTN).

The ASTS is a medical society of close to 700 transplant surgeons whose members perform the vast majority of organ transplants in the U.S. The ASTS has developed a consensus position on the OPTN regulation that is included in my written testimony. There are some important aspects of the regulation which ASTS strongly supports, but there are others that we feel do not benefit the patients we serve.

There are several key points that I would like to emphasize in my oral testimony today.

1. The two aspects of the proposed rule which surgeons most strongly and uniformly support—standardized listing criteria and standardized criteria for determining the medical status of patients awaiting a transplant—are already being used by all liver transplant programs in the United States.

When I testified before a Joint Senate-House hearing on the OPTN rule almost three months ago, I suggested that seeing that the same criteria ARE being used by ALL transplant centers—coupled with better enforcement—might go a long way toward resolving the concerns of those who have focused on perceived geographic differences in waiting times for the most seriously ill patients awaiting liver transplants.

I suggested on June 18th that in fact, it might well already be the case that waiting times had already become relatively equal throughout the country for our most critically ill patients.

Today, with data for 1998 through the month of August now available, I would like to call the Committee's attention to the fact that for Status One patients, the most critically ill, the mean waiting time for a transplant—across the country—now is running four days, with not a great deal of regional variation. For example, the mean waiting time in my state, California, during this period was two days. The mean waiting time in Pennsylvania was five days. The mean waiting time in New York was two days. The mean waiting time in Florida was three days. The mean waiting time in Texas was two days.

Let me additionally say that many of us in the transplant community do not believe that time on a waiting list is necessarily the best indicator of a fair organ allocation system. But the Department of Health and Human Services—while privately conceding to us that waiting times might not be the best proxy for fairness—has made it clear that they intend to stick to this rationale for implementing a rule that would dramatically restructure organ allocation policy.

Well, that being the case, I would suggest that the rationale for rushing this rule into effect may largely have disappeared.

That brings me to my second point.

2. We have for some time now been trying to point out that the Department's apparent determination earlier this year to give priority to sickest patients first—without geographic consideration—would in fact be detrimental to the goal of providing the most Americans with life-saving transplants.

This policy, which has been modeled for liver transplantation, has actually been shown to have significant disadvantages to alternate systems, including the current one. Giving priority to sickest first over broad geographic areas would be wasteful and dangerous, resulting in fewer patients transplanted, increased death rates, increased retransplantation due to poor organ function, and increased overall cost of transplantation.

The Department in subsequent discussions with our society has told us that in fact, giving priority to sickest patients first—in effect, creating a single national waiting list—is not the intent of the rule. Nevertheless, they have not changed the rule to make it clear that it would not require transporting organs across broad geographic areas.

One additional problem with requiring broad geographic transportation of organs is that it would curtail the use of the new split-liver technique, in which a single organ is divided to provide transplants for two recipients. Full utilization of this split-liver procedure would potentially increase available donor livers by close to 1,000 per year in the U.S.

Just this summer, I have performed 10 split-liver transplants—providing a new chance at life to 5 additional Californians who otherwise would undoubtedly still be lingering on the waiting list.

This is not to say that alternatives to the current allocation policy should not be considered. We wish to emphasize that this is exactly the process for the OPTN, namely to thoughtfully reevaluate the existing policy as new data becomes available.

I would like to make a final point before concluding my oral testimony.

When I appeared before Congress on June 18th, I made it clear that our Society of transplant surgeons was prepared to work as intensively as possible with the Department of Health and Human Services to resolve our concerns—which are enumerated in our position paper, and many of which I have not discussed in my oral testimony—if the Department's objective remained to put a new OPTN rule into effect on October 1.

After communicating to them our concerns, we have waited quietly—not taking our story to the media; not taking our story to Members of Congress—while talks took place between the Department and UNOS which we hoped would result in a satisfactory resolution of these important issues.

Now, almost three months later, and only days before the rule is scheduled to take effect, we have not been informed of any specific proposed changes in the OPTN rule that would address areas of critical importance to ASTS.

In the final analysis, the surgeons who are members of our society are the medical professionals who took the vow to First, Do No Harm. We believe the OPTN rule, as it stands, would harm a system which we have tried to make as fair as humanly possible.

We have serious concerns about the language in the rule as it now stands which—in the final analysis—would permit substitution of the Secretary's judgment on organ allocation for the judgment of medical professionals. We do not believe this is what was intended by Congress when it enacted NOTA, and we urge the Committee to block implementation of the rule as it now stands.

AMERICAN SOCIETY OF TRANSPLANT SURGEONS—POSITION PAPER

Introduction

On April 2, 1998, the Secretary of the Department of Health and Human Services issued a final rule governing the Organ Procurement and Transplantation Network (OPTN). The American Society of Transplant Surgeons (ASTS) has discussed the merits of this final rule among its members and council, and has formulated a position on these regulations. There are areas of agreement, as well as disagreement, with the rule as written. We believe that our collective experience as transplant surgeons, involved and committed to the care of the transplant patients, qualifies us to comment with perspective on these regulations because of their direct impact on our patients' lives. ASTS wishes to participate in constructive dialogue, and is appreciative that Congress has extended the comment period until August 31, 1998 and delayed implementation of the regulations until October 1, 1998. We are hopeful that modifications to the final rule can be agreed upon by all concerned parties prior to any implementation so that our patients can best be served.

It is the goal of ASTS, first and foremost, to see that as many as possible of the growing number of patients waiting to benefit from a transplant actually receive this opportunity for a new chance at life. As long as there continue to be fewer organs available than there are patients awaiting a transplant, the ASTS believes

public transplant policies should support the primary goals of: (1) expanding and enhancing organ donation throughout the United States through education and legislative initiatives, and (2) insuring that the precious organs presently available provide the maximum benefit to the maximum number of Americans in an equitable fashion.

It is the consensus of ASTS that the rule issued by HHS should be more definitively clarified to address these two issues since it may unintentionally work against these national goals.

Organ allocation policy development

ASTS would first like to emphasize that we believe the National Organ Transplant Act (NOTA) which was passed by Congress in 1984 and established the OPTN in the private sector under government contract, intended for the OPTN to make organ allocation policy based on sound medical principles and scientific data independent of political influence. To that end, the current OPTN contract holder, the United Network for Organ Sharing (UNOS), has established clearly defined roles and responsibilities that involve a broadly representative group of individuals with expertise and interest in transplantation and the patients we serve. For the most part, ASTS believes this system has succeeded and ASTS supports the system. But ASTS also believes that UNOS' performance as the OPTN contract holder requires continuous re-examination and refinement. ASTS agrees that the HHS, as the grantor of the OPTN contract, has oversight responsibilities, but ASTS believes that HHS should not attempt to dictate medical practice. As discussed in more depth in this document, ASTS does not believe HHS should be involved in making, modifying, or vetoing organ allocation policy unless directed to do so by law.

Allocation of organs

The HHS final rule sets three broad performance goals for organ allocation including: (1) standardized listing criteria for placing patients on waiting lists using objective and measurable medical criteria; (2) standardized criteria for determining medical status using objective and measurable medical criteria that will differentiate patients from the least to the most medically urgent; and (3) organ allocation policies that give priority to those whose needs are most urgent with the result that differences in waiting times for patients in the same medical status category will be reduced.

Standardized listing criteria

ASTS strongly agrees with the provision calling for standardized listing criteria. It should also call for standardized de-listing criteria. Only when standardized listing and de-listing criteria, and standardized criteria for determining medical status, are universally applied by all centers will waiting times become more interpretable over time as one measure of equity of allocation policy. In fact, ASTS, UNOS and its Board and committees, and the transplant community have already recognized the need for standardized criteria and have acted appropriately. In order to equitably allocate and distribute the scarce organs, a well-defined procedure for entry to and exit from the waiting list is required. Standardized listing criteria are in place for heart and kidney recipients. Standardized listing criteria for liver transplant recipients were developed by the Liver and Intestinal Organ Transplantation Committee of UNOS and subsequently approved by the UNOS Board. These criteria were implemented in 1997 and are currently assumed to be in use by all liver transplant programs in the U.S. Monitoring of this should be taking place even now. If non-compliance is determined, enforcement by appropriate sanctions should be recommended by UNOS and implemented by HHS.

These standardized listing criteria will need ongoing refinement as medical practices change and more data on patient survival becomes available. The ASTS is supportive of the process by which these criteria are developed and modified, and supports the development of standardized listing criteria for all transplanted organs.

Standardized criteria for determining medical status

The ASTS agrees that the same objective medical criteria should be utilized by all transplant centers to determine the severity of a patient's illness, and that the status classification scheme should be as unambiguous as possible. There has been an ongoing effort within UNOS to refine the medical status categories for liver transplant candidates as the field of transplantation has evolved. Even further refinement of this process is to be anticipated. We would support a rapid review system whereby all patients being listed at any status would need approval, and an appeal process for controversial patients should be available.

Organ allocation policies that give priority to those whose needs are most urgent. There have been different and conflicting conclusions drawn about approaches to

organ allocation, depending on favored theoretical modeling systems, that cannot truly take into account progress in this rapidly evolving field. There has been general consensus in UNOS based on such modeling, but there have also been outspoken minority viewpoints. We believe the allocation policy for livers needs continuous evolution based on the most current knowledge, which can only be reflected by the expertise of those deeply involved in the field.

Based on this expertise, we do not believe that a single national list of liver distribution is realistic or necessary to achieve an equitable distribution system. Furthermore, we do not believe it is in our patients' best interest. As it now stands, ASTS believes that a single national list giving priority to "sickest first" would be wasteful and dangerous, resulting in fewer patients transplanted, increased death rates, increased re-transplantation due to poor organ function, and increased overall costs of transplantation.

On the other hand, there are alternative distribution systems to be examined that may enhance distribution equity. ASTS also recognizes that within regions, there are issues of inequity that UNOS should have the will and authority to address and facilitate correction. These are issues that should be continuously re-examined by UNOS. We wish to express our willingness and desire to be involved in this process. Until the organ supply meets the organ demand, no perfect solution will ever be achieved that will provide access to organs for all patients who need them.

Transition to new policies

ASTS agrees with the Secretary that when the OPTN revises allocation policies, provisions must be made to ensure that patients already on the waiting list for transplantation are not disadvantaged by the new policy.

OPTN Board composition

The final rule mandates an OPTN Board size of at least 30 members, and specifically requires that 4 of these members be transplant surgeons or transplant physicians.

We have always supported the inclusion of transplant recipients, donor families and other members of the general public on the OPTN Board. As you know, this is already the case. However, ASTS respectfully submits that because of the technical and scientific as well as ethical and social problems continuously presented by this field, transplant surgeons and transplant physicians should constitute no more nor less than 50 per cent of this Board. The final regulation simply does not allow for this in a practical way.

On a related note, we wish to observe that ASTS considers it essential for HHS officials and the OPTN to develop a closer working relationship. While this need not be viewed as requiring a government representative on the OPTN Board, it probably does mean that senior HHS representatives should regularly attend OPTN meetings and maintain a constructive dialogue with the OPTN Board and staff.

Public access to data

ASTS agrees with the Secretary that physicians, patients, and the public should have access to accurate, understandable, and timely information regarding transplant center performance. We believe that data should be collected annually, and be made available to HHS and the public within one-year after the period to which they apply. We agree that these data should include general transplant center and program information, actuarial patient and graft survival rates, re-transplant rates, waiting times, rates of non-acceptance of organs, and other data that would be helpful for physicians, patients, and their families in making transplant decisions. The transplant community must be given the opportunity to review and present the data in such a way as to avoid misinterpretation, and the Secretary should provide assurances that any release of data conforms to the laws and regulations governing the OPTN and that patient confidentiality will be preserved.

Secretarial oversight

ASTS would be pleased to work with the Secretary to develop a process that would preserve the Secretary's legitimate oversight role while allowing a reasonable level of input by various stakeholders, specifically including surgeons, other physicians, and patients actively involved in transplantation. In suggesting this, however, we wish to stress our view that organ allocation and other OPTN policies should generally, if not always, be developed through an ongoing consensus process under which the relevant scientific, clinical, and ethical factors are considered.

Review and evaluation

ASTS strongly agrees that allocation and other policies, such as standardized listing criteria, must be enforced. The regulation notes (in section 121.10) that enforce-

ment would involve relatively harsh penalties, including termination of a transplant hospital's participation in Medicare or Medicaid, or termination of a transplant hospital's reimbursement under Medicare or Medicaid. We believe that the regulation should provide an opportunity for due process and corrective action, and the initial use of time-limited intermediate sanctions, prior to the imposition of severe sanctions such as withdrawal of center Medicare and Medicaid reimbursement.

Reducing socioeconomic inequities

ASTS certainly believes that medical criteria should be the sole determinant of access to transplantation. Section 121.4 of the final rule requires the OPTN to develop policies that reduce inequities resulting from socioeconomic status. We recognize that many Americans lack health insurance coverage. Nevertheless, we view this as a societal issue rather than one that can easily or independently be addressed by the OPTN, or by individual transplant centers and professionals.

Promoting organ donation

Finally, ASTS wishes to emphasize that the true solution to this ethical and medical dilemma lies in increasing the supply of these life-saving organs in our country. We strongly believe that this is possible through just legislation and through devotion of additional resources which, to date, have not been forthcoming. We believe it is in this area that the ASTS can be most helpful and wish to express our eagerness to carry this initiative forward.

STATEMENT OF CRAIG J. IRWIN, PRESIDENT, NATIONAL TRANSPLANT ACTION COMMITTEE

Senator SPECTER. We now turn to Mr. Craig Irwin, president of the National Transplant Action Committee.

Mr. IRWIN. Thank you, Mr. Chairman.

In 1996, this body stated, the original intent of the National Organ Transplant Act was to assure patients that no matter who they were or where they lived, they would have a fair chance for receiving an organ transplant.

Today the sense of the Senate as embodied in those words is not being carried out. In fact, accidents of geography account more for who receives a transplant than medical necessity.

Mr. Shay Colamarski from Spokane, WA, was a working and productive young man when he found out he had hepatitis B and needed a liver transplant. He was denied a transplant in Washington and had to go to San Francisco, where he waited for nearly 2 years. The waiting time in Washington was only about 9 months.

Mr. Colamarski received his transplant 1 year ago last week and is with me today. Ask him if the system is fair to patients.

Jordan Rosebar was not so fortunate. On June 1 she was listed at hospitals in Pennsylvania and Florida in the most urgent category, status 1. Two organs were found that evening. One stayed in Louisiana. The other went to healthier patient in a different Florida hospital. Jordan died early the next morning. She was only 18 months old.

Each of these stories help illustrate the problems with the current organ allocation system. Like Mr. Colamarski, about one in four patients travel outside of their State for a transplant. Even though patients migrate, our current system of allocation is based upon local first.

As a result, patients are not treated fairly. Their chance to receive an organ varies dramatically from city to city and from State to State. The medical concept of triage is an important one. Those who can benefit the most from health care receive priority treatment.

But as young Jordan Rosebar's case illustrates, geography, not medical urgency, is the key factor in the current organ allocation system. Clearly, the OPTN is not working. The system is not fair.

For nearly 6 years the allocation debate has raged within the transplant community. Unfortunately, the welfare of patients waiting for transplants have been largely ignored in this debate. And so significant improvements have not been made in the system.

However, at the same time, HHS has been working on final rules governing the OPTN. The rules set clear performance objectives for the OPTN that will promote equity and are consistent with the medical principle of triage.

Once again, the Senate stated the United States should have a consistent and fair system of organ allocation and move away from the persistent fragmentation and inconsistency that may have evolved despite the National Organ Transplant Act.

The Secretary's regulation does exactly that. While negotiating on one hand, UNOS is fighting the regulations on the other. While this debate rages, patients are dying needlessly. The system is not fair.

UNOS serves two masters, profits for its members and the needs of patients. HHS has only one, the needs of patients. UNOS lacks the resolve to address these problems, instead putting profits ahead of patients. These regulations cannot be delayed any longer.

PREPARED STATEMENT

Once again, Mr. Chairman, I conclude citing the Senate's own words, It is time for the final rule to be issued. The final rule is viewed by the Senate to be of highest priority. I hope these words still ring today.

Thank you.

Senator SPECTER. Thank you very much, Mr. Irwin.

[The statement follows:]

PREPARED STATEMENT OF CRAIG IRWIN

The National Transplant Committee [NTAC] respectfully submits its comments to the Senate Appropriations Committee, on its hearing concerning the governance of the U.S. Organ Procurement and Transplantation Network [OPTN]. NTAC is a consumer advocacy organization with approximately 1500 members across the United States. NTAC was founded 1992 by organ transplant patients and advocates interested in public policy issues and decisions that impact organ transplant patients and their families. NTAC is not directly affiliated with any transplant centers or professional organizations.

NTAC and its principals have a long history of involvement with the National Organ Transplant Act [NOTA] and federal organ transplant policy. One of the current NTAC directors was involved with the original 1983 Congressional hearings that eventually led to the establishment of the OPTN. Since then, NTAC officers and directors have testified at Congressional hearings in 1990, 1993, and 1995. In 1995, NTAC was the only transplant patient advocacy organization invited to testify at hearings on NOTA before the Senate Committee on Labor and Human Resources.

NTAC has also closely monitored and participated in the development of the Final Rule on the OPEN that is the subject of today's hearing. NTAC submitted a comment on the proposed rule in 1994 and participated in hearings conducted by the Department of Health and Human Services in December 1996. In addition, we have also participated in deliberations conducted by the OPTN contractor pertaining to the allocation of organs for transplantation. In September 1996 NTAC participated in a forum conducted by the OPTN contractor on the allocation of livers for transplantation.

NTAC supports the final OPTN rules as published by HHS. We believe that the rules are consistent with the intent of NOTA and that they serve the best interest of the public health, organ transplant patients, and organ donor families.

While supporting the final rule, NTAC also has grave concerns about the misinformation and lobbying activities conducted by many doctors and professionals in the transplant industry as well as the OPTN contractor. We feel that these activities have needlessly inflamed and frightened transplant patients and their families. The contractor's efforts to stop or delay the implementation of these rules is reprehensible and should be a factor considered by the Congress in any future deliberations regarding the OPTN contractor and contract.

HHS AUTHORITY TO OVERSEE THE OPTN

NOTA was enacted by Congress in 1984 in order to establish a national system, based upon medical criteria, of matching organ donors and patients needing transplants. Although NOTA mandated that the OPTN operate under the management of a "private, non-profit organization," the act also requires the Secretary to maintain a unit within the Public Health Service to "administer [the act]."

Because of the role given to the private contractor under NOTA, some have argued that the intent of Congress was to create an independent private network free of government intervention. In 1990, Congress amended the act in order to provide the Secretary with greater flexibility in contracting for the operation of the OPTN. This amendment clearly places greater responsibility and authority within HHS to oversee the operation of the OPTN. NTAC believes that there is an important role for the Secretary and the Department of Health and Human Services in the operation of the OPTN and that the Final Rule is consistent with the Congressional intent of NOTA.

Although Congress has not amended NOTA since 1990, in 1996 the U.S. Senate, under the leadership of Senators Frist and Kennedy, unanimously passed the Organ Transplant Reauthorization Act of 1996. As part of its report, the Senate stated that "It is the committee's belief that a portion of the public distrust [of the organ transplant network] is an indirect result of the failure of the government to issue final rules governing the policies and procedures for organ transplantation. Else committee believes that it is time for the final rule to be issued and that the call for final rules, which has spanned more than 6 years, needs to be brought to closure. The "final rule" is viewed by the committee to be of highest priority."

NTAC believes that HHS serves a vital role in organ transplant policy in the United States. Congress has also stipulated a clearly defined role for HHS. We believe that the rules now under consideration are consistent with NOTA and serve the best interest of transplant patients and the public.

SPECIFIC PROVISIONS OF THE REGULATIONS

Section 121.3.—The OPTN

NTAC supports all the provisions of this section of the regulation and especially those sections pertaining to the composition of the board and qualifications for membership in the OPTN.

NTAC has long held the view that there is a great measure of conflict among all board members of the OPTN between their personal/institutional interests and those of the transplant patients. As stated in the preamble of the rule, organ transplantation has become a \$3 billion industry in the United States. Organ transplant centers, physicians and surgeons all have a vested financial stake in the public policies developed by the OPTN. These decisions can translate into millions of dollars for a single institution. In addition, a health care facility's ability to maintain a viable organ transplant program can also translate into millions of additional dollars through other grants and contracts.

These financial incentives to maintain a viable transplant program can bias critical public policy decisions. Since its inception, the OPTN has maintained a board of directors made up predominantly of physicians and surgeons in the transplant industry. We believe that the OPTN board composition hinders thoughtful public policy. Nowhere has this been more evident than in OPTN policies governing organ allocation.

NTAC supports section 121.3(a) in its entirety. The inclusion of six members of the general public on the OPTN board of directors (paragraph (a)(1)(iv)) will ensure that the policies of the OPTN will continue to serve the public's health care interest. Furthermore, limiting surgeon and physician membership on the board to 50 percent combined with a minimum requirement that 25 percent of the board consist

of patients, donors, and families members, will help protect the interests of the transplant patients.

It has been argued that patients, donors and family members already represent more than 25 percent of the OPTN board. Although this may be true, it is also true that oftentimes these "public" members of the board have been medical doctors or had some additional professional interest in organ transplantation. It has also been argued that a high degree of professional and medical expertise on the OPTN is necessary in order to effectively deal with the complex medical decisions required of the OPTN board of directors. In truth many of the issues facing the OPTN board involve broad public policy decisions where a medical background and education is not critical. A framework to provide medical guidance and input to the board of directors is sufficient to assist the board with understanding the medical factors that impact their public policy decisions.

In addition to the overwhelming influence of medical professionals on the OPTN board, the OPTN membership is also strongly biased toward transplant professionals. At present there are fewer than 10 "general public members" of the OPTN contractor. Section 121.3(c)(2)(iii) will provide any interested parties with an opportunity to become a member of and participate in the OPTN. This will result in broader participation in the selection of OPTN board members and provide protections that the policies of the OPTN will serve the public health care interest without the influence of financial conflict or bias.

Section 121.11.—Record maintenance and reporting requirements

There are many factors that impact the likelihood of receiving and saving an organ transplant. Among these are the experience and historical performance of the transplant center, the acceptance and turn down rate of donated organs, as well as the length of an institution's waiting list. NTAC believes that there is a broad range of critical data that must be made available to the public and to transplant patients. This information must be timely and accurate.

Also, it is important that the public be able to evaluate and monitor the impact of public policy decisions on organ transplant patients as well as assess the performance of the OPTN contractor. This requires access to a wide range of critical data.

The current OPTN contractor's system of record maintenance and reporting is insufficient to meet the critical needs of patients, the public, and those with an interest in the public policies of the OPTN. It has been our experience that important data is often withheld without good reason. The current OPTN contractor has used arguments such as "patient confidentiality" and "the data has not been verified" to defend its refusal to make available critical data. However, it is our belief that these "defenses" have been nothing more than a tool to guard the OPTN contractor or individual OPTN members from scrutiny or criticism.

The OPTN last published the center specific survival report in 1997. The data used in the analysis only included transplants performed through 1993. As a result, the report included many qualifying letters from transplant centers providing their most recent patient survival results. Unfortunately, these updates are meaningless unless they are reported in the risk-adjusted format of the center specific report itself and in a manner that enables individuals to compare transplant performance in some meaningful way. What makes this matter even more critical is the fact that it is oftentimes transplant centers with poorer outcomes that use these "updates" to report more recent and more favorable results.

NTAC believes that maintaining patient confidentiality is important and is confident that HHS will ensure that the individual privacy and confidentiality of transplant recipients will be protected under the rule's expanded reporting requirements. The OPTN rule would ensure that critical data be made available to patients, families, advocates, and other interested parties. The availability of this data will make it possible for patients to be better informed about transplant centers and possible options at the time of transplant. Furthermore, the rules will facilitate the appropriate monitoring of the transplant system as a whole.

Section 121.8.—Organ allocation

Over the past two decades, organ transplantation has proven to be an effective means of treating patients with end stage organ failure. Unfortunately, there are not enough organs to save everyone. Despite efforts within the transplant community to increase donation, the number of organs available has grown only about 1 to 2 percent per year. In the meantime, the number of Americans waiting for organ transplants is now approaching 60,000.

NOTA was enacted so that "an equitable policy and system [would exist] so that individuals throughout our country can have access to organ transplantation when appropriate and necessary." Congress created the National Task Force on Organ

Procurement and Transplantation whose responsibility it was to develop recommendations that would lead to a “truly national, coordinated mechanism for efficient distribution of all available organs.” (Senate Report No. 98-382 and House Conference Report No. 98-1127, U.S. Code Cong. And Adm. News, p. 3975)

In its report, the Task Force recommended that “donated organs be considered a national resource to be used for the public good.” The Task Force also recommended that “selection of patients both for waiting lists and for allocation of organs be based upon medical criteria that are publicly stated and fairly applied.”

However, there is a growing list of publications and reports that have all concluded that the nation’s organ allocation system is not fair and that standards other than medical criteria often decide who receives an organ transplant. According to the most recent reports, the system takes its biggest toll on minorities and children.

On June 1, Jordan Rosebar was listed in the most urgent category, Status I, at a hospital in Pittsburgh, PA. In a desperate measure, surgeons also listed her at the University of Miami Medical Center in Florida. Within hours, two sets of organs were known to be available from the organ procurement organization serving the Miami region. No one was more critical than Jordan was. But, because she was physically in Pittsburgh, the current system prohibited those organs from being shipped to save Jordan. However, one organ stayed in Louisiana while the other was to be transplanted into a patient in the lowest priority category at a Florida hospital. Jordan died early the next morning. Jordan Rosebar was 18 months old.

NTAC enthusiastically supports Section 121.8 of the rule governing organ allocation. The rule establishes a public policy objective in lieu of proscribing a specific organ allocation model. We believe that the HHS rule establishes an appropriate public policy while allowing medical professionals to develop the necessary medical criteria for organ allocation. Also, the HHS rule provides flexibility so that organ allocation policies may quickly be modified to meet any future changes in medical technology.

The objectives stated in the rule will not only improve the equity of the system consistent with the intent of Congress and the National Task Force; it will also save lives in two important regards. First, computer simulation modeling has illustrated that a system of improved equity based upon medical standards will result in patient’s living longer lives. Second, the results of a poll completed for NTAC by the Gallup Organization found that nearly 1 in 3 Americans would be more willing to consent to organ donation if they knew that the organs would go to the patients who needed them the most regardless of where they lived. The HHS rule will foster greater public confidence and support in the nation’s transplant system.

We believe the rule to be in the best interest of transplant patients and the American public. It concerns us that many professionals in the transplant community have attempted to inflame transplant patients and the public through misleading statements. Their goal is to maintain a system that serves many transplant programs well while serving the public health care interest poorly.

Opponents have charged that the rule will result in the closure of transplant centers and harm patient access to transplantation. There is no evidence to support this. Using UNOS modeling data, NTAC has examined the net impact of greater organ sharing and greater equity in liver allocation. We have found that there will be minimal impact, if any, on patient access to transplants. The majority of the transplant centers will continue to be those that annually perform 25 to 100 transplants.

Opponents have also argued that broader organ sharing will have an adverse impact on organ donation. In a poll conducted for NTAC by the Gallup Organization 83 percent of those who responded agreed that organs “should go to the sickest patient in the U.S. no matter where they live.” Also, 32 percent said that they would be more likely to donate an organ if they knew that the organ recipient was the sickest person, regardless of location.” NTAC believes that the HHS rule will have a positive impact on organ donation by fostering greater confidence in the organ allocation system.

Opponents have argued that more patients would die if there were greater organ sharing to create equity. The bulk of the evidence supports just the opposite. Currently, “healthier” patients on the waiting list often receive transplants while sicker patients wait and die. For healthier patients, there are other health care options that can prolong life, improve a patient’s quality of life, and delay the need for an organ transplant. For the sickest patients—there is no other option but transplantation.

Although we are supportive of the allocation section of the rule, we have concerns over the enforcement of the public policy directive. The current OPTN contractor has shown a resistance to positive changes in the organ allocation system despite growing evidence that the current system is not fair and despite pleas from patient

support groups for change. It is our hope that the Secretary and the Department will aggressively enforce the organ allocation policy established in the rule and ensure that the OPTN contractor complies with the rule as published.

We believe that the organ allocation policy established by HHS will serve patients well and foster the development of a system that is fair and equitable to all Americans needing organ transplants.

SUMMARY

The rule making process has extended a number of years. NTAC believes that the resulting rule is the result of a great deal of research and thought on the part of the Department of Health and Human Services. The policies established by HHS will provide a strong voice for patients and the public in this very important sector of the health care industry while still providing doctors and other medical professionals the needed flexibility to make health care decisions in consultation with their patients.

The regulations will also ensure the national system of organ allocation and transplantation that was envisioned by Congress in 1984 and is still the goal today.

The original intent of the National Organ Transplant Act was to assure patients that no matter who they were or where they lived, they would have a fair chance of receiving an organ transplant. It is the belief of the committee that the United States should adopt a consistent and fair system of allocation and move away from the persistent fragmentation and inconsistency that may have evolved despite the National Organ Transplant Act."

"It is the committee's belief that a portion of the public distrust [of the organ transplant network] is an indirect result of the failure of the government to issue final rules governing the policies and procedures for organ transplantation. The committee believes that it is time for the final rule to be issued and that the call for final rules, which has spanned more than 6 years, needs to be brought to closure. The "final rule" is viewed by the committee to be of highest priority."

National Transplant Action Committee supports the OPTN Rule and looks forward to working with the Department of Health and Human Services toward its successful implementation. We hope that the Congress will allow the current process to move forward so that all Americans' regardless of who they are or where they live, will have a fair and equitable opportunity to find a donor when they need an organ transplant.

STATEMENT OF CHARLES M. MILLER, M.D., DIRECTOR, THE RECANATI-MILLER TRANSPLANTATION INSTITUTE

Senator SPECTER. We now turn to Dr. Charles Miller, director of the Recanati-Miller Transplant Institute, Mount Sinai Hospital, New York.

Welcome, Dr. Miller. The floor is yours.

Dr. MILLER. Good morning and thank you, Mr. Chairman, for the opportunity to address the committee.

Today, based on my 15 years of experience as a transplant surgeon, I would like to give you my personal view of these complex issues in transplantation, voice my strong support for the rule issued by HHS, and convince the committee that it should be implemented without delay.

The rule states, "Geography cannot remain a primary criteria in organ allocation. Where you live cannot determine whether you live or die."

Presently, there are 63 areas served by local organ procurement organizations. And the boundaries that these make make our organ allocation system inequitable, because medical urgency and length of time waiting are rendered less important than where the organ is procured.

Livers, for instance, are preferentially given to local patients, even if there are sicker patients just across an OPO border in a neighboring community. For example, a liver in New Jersey, where I live, parenthetically, might be used in Newark for a patient wait-

ing comfortably at home while a patient across the river in New York is dying in the ICU. And vice versa. Such accidents of geography should not continue.

The link between organ distribution and OPO boundaries dates from the infancy of transplantation, when organ preservation techniques did not allow safe distance sharing of organs.

Today there is no logic in remaining confined to local distribution areas. We need to bring our system up to our science. By sharing organs beyond where they are procured, the playing field will be leveled for patients and fairness achieved.

Now, broad sharing in a national system is not the same as a single national waiting list. A single list is just one type of national system. While it ensures equity, it would also require the most extreme change, from these 63 subsystems to just 1. And the transplant community, and I agree with Dr. Busuttil, agrees that a single national list is not necessary to achieve reasonable equity.

The systems based on population densities or larger super regions would provide for more flexibility, economies of scale and community acceptance. Any such potential system is possible under the new rule, as it does not mandate any specific system. It merely makes equity for patients the primary objective.

What about the concept of caring for the sickest patient first? Now some opponents of the new rule claim that the concept portends utilitarian disaster, that fewer lives will be saved.

But caring for the sickest first does not mean wasting scarce organs, because the new rule also demands utility to minimize organ wastage. It calls for a system to discourage transplantation of patients with no reasonable hope of survival.

Interestingly, each OPO already employs a sickest first policy. And our ability to care for transplant candidates and to identify patients with no reasonable chance of survival has improved dramatically in recent years.

UNOS has already instituted, and we must continue to refine, specific criteria for placing patients on or removing them from the waiting list and for prioritizing them according to medical urgency. Employing such criteria many more lives will be saved with broader sharing and timely transplantation of the neediest patients.

Two other commonly expressed fears regarding the new rule are that smaller transplants will have to close and that organ donations will decrease. But there is no evidence, no evidence, to support either of these concerns. With respect to small centers, there is actually some evidence that they will do better.

It is much more likely that transplant centers will open or close on the basis of factors other than allocation, including reimbursement issues, quality issues, institutional support, and local competition for patients.

PREPARED STATEMENT

I also believe that the HHS rule will actually lead to increased organ donation, as the public begins to trust that organs will be dispensed fairly. Three opinion polls have clearly shown that donor families want organs to go to patients who need them the most, and they do not care—

Senator SPECTER. Your red light is about to go on. Would you summarize, please, Dr. Miller?

Dr. MILLER. Yes, sir.

In summary, the HHS rule is a flexible, patient-sensitive plan. The long debate over organ allocation has outlived its usefulness. Let us enfranchise the public and save more lives by allowing the rule to be implemented without delay.

Thank you.

Senator SPECTER. Thank you very much, Dr. Miller.

[The statement follows:]

PREPARED STATEMENT OF DR. CHARLES M. MILLER

Good morning. Thank you for the opportunity to address the committee. My name is Charles Miller. I am a transplant surgeon. I am also the physician-in-chief of transplantation services at the Mount Sinai Hospital in New York City, and Director of the Transplantation Institute at the Mount Sinai Medical Center. I have been part of the national discussion regarding organ donation and organ allocation for over seven years. As a member of UNOS, I have served on its many committees, including its organ allocation committee, for over five years. From 1994 to 1996, I was a member of the UNOS board of directors. In addition, I have been a member of the American Society of Transplant Surgeons for more than 10 years, and I have worked within that organization to help formulate a rational and balanced position on these issues. At the request of Barbara DeBono, New York State's Commissioner of Health, I have also chaired, for the past year, the State's task force to increase organ donation.

Today I'd like to give my personal view on the complex issues of allocation and donation, voice my strong support for the rule issued by Secretary Shalala, and convince you that her thoughtfully conceived plan should be implemented without delay.

In general, I see little need for governmental intervention in our field. However, I am troubled by our community's lack of success in developing a fair allocation system, despite in-depth analysis and computer modeling, and I am concerned about the destructive publicity that the debate has caused and its negative effect on organ donation. For over seven years now, the transplant community has struggled unsuccessfully to develop a system for allocating organs that is fair to all patients. We have made some progress, but unfortunately we have not resolved one of the most fundamental questions: Are donated organs a local commodity or a national treasure to be distributed based on patient need?

The dispute within the transplant community has reached the point where governmental input and mediation is required, to establish and confirm that the prime consideration in organ allocation is not where one lives but rather one's medical need and reasonable chance for survival.

Secretary Shalala wrote, "Geography cannot remain a primary criteria in organ allocation. Where you live cannot determine whether you live or die." Illness knows no geographic boundaries. Neither should organ allocation. Presently, however, organ allocation is based primarily on narrow geographic boundaries—the 63 areas served by local Organ Procurement Organizations [OPO]. These boundaries make our organ allocation system inequitable, because medical urgency and length of time waiting are rendered less important than where an organ is procured. Livers are preferentially given to local patients, even if there are sicker patients across an OPO border in a neighboring community. For instance, a liver in New Jersey might be used in Newark for a patient waiting at home, while a patient across the river in New York is dying in the ICU. Or vice versa. Such "accidents of geography" happen all the time without our knowing it, because there are almost always local patients who can use an organ, and the system does not in the first instance look for recipients outside of the local area. The link between organ distribution and OPO boundaries dates from the infancy of transplantation, when organ preservation techniques did not allow safe, distant sharing of organs. Today, there is no logic in remaining confined to local distribution areas. We need to bring our system up to our science. Once the primacy of geography is nullified by the new rule, we have the ingenuity and ability to develop equitable formulas for allocation. By sharing organs beyond where they are procured, the playing field will be leveled for patients with equivalent disease severity across the entire country.

I would also like to briefly discuss several other issues raised by the final rule that are causing concern in the transplant community.

I want to emphasize that broadening sharing in a rational national system is not the same as having a single national waiting list. Why are the terms “single national list” and “national system” different? A single national list is but one type of national system. For any organ, it is important to understand that broadened sharing in a national system is not the same as a single national waiting list. A single national list would provide the most pure form of equity, but it would also require the most extreme change, from 63 subsystems to 1. For many good reasons, there is broad consensus within the transplant community—with which I agree—that a single national list is not necessary to achieve reasonable equity and is in other ways undesirable. Systems based on population or organ donor densities or large super-regions would provide for more flexibility, economies of scale, and community acceptance. Any such potential system is possible under the new rule, as it does not mandate a specific distribution or allocation algorithm; it merely makes equity the primary objective. What the new rule does mandate, however, is that we finally begin the hard work of designing a new, fair and modern system.

What about the concept of “caring for the sickest patient first?” Some opponents of the new rule claim that this concept portends utilitarian disaster—that fewer lives will be saved and organs will be wasted. But “caring for the sickest first” does not mean wasting scarce organs. The new rule also demands utility, to minimize organ wastage. It calls for a system that discourages transplantation of patients with no reasonable hope of survival. Interestingly, each OPO already employs a “sickest first” policy. Our ability to care for transplant candidates and to identify those patients who have no reasonable chance of survival has improved dramatically over recent years. UNOS has already instituted, and we must continue to refine, specific criteria for placing patients on or removing them from the waiting list and for prioritizing them according to medical urgency. Employing such criteria, many more lives could be saved with broader sharing and timely transplantation of the sickest patients. And it is critical that decisions requiring medical judgment, including such criteria, be made by physicians, not by bureaucratic or political decree.

Two other commonly expressed fears regarding the new rule are that smaller transplant centers will have to close, and that organ donation will decrease. There is no evidence to support either of these concerns. With respect to the question of center closures, I believe that the new rule will be neutral in terms of its impact. If a wider sharing system were instantly enacted, it might temporarily shift organs away from centers with shorter waiting lists toward centers with longer lists, where patients have long waiting times—but in time, as the playing field became level, new patients at small centers would accrue waiting times that were equivalent to those of patients at larger centers. Advocates for some small centers are concerned, however, that the temporary downturn in volume would be so severe that they would not be able to maintain financial or operational viability. This fear is unfounded, because the new rule demands that new policies be put into effect with “transition protections” to assure that patients who are already listed will not be disadvantaged by any new system. During a transition period, centers can adapt in order to remain competitive. It is much more likely that transplant centers will open or close on the basis of factors other than allocation, including reimbursement issues, quality issues, institutional support, and local and regional competition for patients.

In contrast to the oft-stated rhetoric that organ donation will suffer, I believe that the HHS rule will lead to increased organ donation as the public begins to trust that organs will be dispensed fairly. Three opinion polls have clearly shown that donor families want organs to go to patients who need them the most, and that they don’t care about geographic boundaries. The real benefit to the donor family is the opportunity to transform, at least in part, a terrible tragedy into a chance for life for another person, in a process that is still considered by many to be mysterious and miraculous. They feel that the meaning and value of their gift is maximized by making sure that the neediest patients are transplanted first, no matter where they might be.

In summary, our organ allocation system continues to put geographic primacy above patient need. You or I, our spouses or members of our families, could someday be one of these severely ill people. Illness knows no geographic boundaries. Neither should organ allocation.

Secretary Shalala’s rule is a courageous, flexible, and patient-sensitive plan that allows for improved cooperation between the government and the transplant community. The long debate over organ allocation has outlived its usefulness. Enough is enough. Let’s enfranchise the public, by allowing the rule to be implemented without delay.

STATEMENT OF WILLIAM PFAFF, M.D., PRESIDENT, UNITED NETWORK FOR ORGAN SHARING

Senator SPECTER. We now turn to Dr. William Pfaff, president of the United Network for Organ Sharing.

Thank you for joining us, Dr. Pfaff. And the floor is yours.

Dr. PFAFF. Chairman Specter, members of the subcommittee, good morning. I am Dr. William Pfaff, the emeritus professor of surgery at the University of Florida College of Medicine and the current president of the United Network for Organ Sharing. It is an honor and privilege to be here this morning to testify about organ donation and allocation issues that, unfortunately, have become very, very controversial.

Senator FAIRCLOTH. Doctor, would you pull the microphone closer, please?

Dr. PFAFF. Thank you, sir.

We at UNOS are troubled by this current controversy and, like all of you, wish it to end and focus what we need to do best and what do most; that is, working to ensure that organ donation increases and as many patients as possible have access to life-saving transplants.

No discussion of allocation can be complete without mentioning donations. So let me commend HHS and Congress for their recent commitments and efforts to increase organ donation. The Health Care Finance Administration recently issued a regulation requiring all hospitals participating in the Medicare system to follow similar procedures, as have the recent State legislations in Pennsylvania and Maryland. UNOS' board of directors unanimously voted to support the HHS regulation.

As we exist today, UNOS, by its design and in its role as the organ procurement and transplant network contractor, has developed a consensus-based policymaking process that is intended to continually evolve and innovate in response to technological advances, changes in donation rates, and other developing circumstances. We provide a national forum for establishing sound consensus-based medical guidelines for transplantation and distribution of organs.

Organ procurement distribution policies are continually challenged and verified within this process to ensure that most is made of the scarce and precious resource or donor organs. The transplant community's policies are published for public comment and are ultimately reviewed and approved by HHS.

At issue here is the April 2, 1998, Department of Health and Human Services regulation governing the activities of the transplant network and laying out a framework for a new organ allocation system and processes by which transplant policy is made.

To summarize our concerns, UNOS believes, No. 1, the regulation, as written, is subject to misunderstanding and conflicting interpretations and could potentially cause harm to patients.

No. 2, clarification by Congress is needed to resolve the possible conflicts between the regulation and the National Organ Transplant Act, as highlighted by the AMA in its written comments to the Department.

No. 3, the regulation must reflect the intent of NOTA that OPTN governance and policy issues be determined by the OPTN with oversight by HHS.

No. 4, we think the regulation should be delayed until it is rewritten to clarify the Department's intent and make other necessary changes.

Since the June 18 joint meeting, we have had five productive meetings with top HHS and HRSA officials to discuss a number of our specific concerns, including the intent of some of the language which appears in the regulation. We were pleased, for example, to learn that the Department does not intend to require a national sickest patient first allocation system. But we continue to be concerned that this interpretation is not adequately reflected in writing within the regulation.

Our meetings have been fruitful in clarifying the Department's intent and interpretation with regard to other specific aspects of the regulation. However, these discussions have not been completed.

PREPARED STATEMENT

UNOS firmly believes that all clarifying interpretations must be reflected within the regulation. Without such changes, the transplant community, patients and donor families are left wondering and worrying about fundamental components of organ procurement and allocation policy. We are hopeful that continued discussions with HHS will bring our resolved issues to resolution.

So on behalf of HHS, we thank you for inviting us to participate in the hearing today. I would be happy to answer any of your questions.

Senator SPECTER. Thank you very much, Dr. Pfaff.
[The statement follows:]

PREPARED STATEMENT OF DR. WILLIAM W. PFAFF

Chairman Specter, members of the Subcommittee, good morning. I am Dr. William Pfaff, Professor Emeritus of Surgery at the University of Florida College of Medicine and current President of the United Network for Organ Sharing (UNOS). It is an honor and a privilege to be here this morning to testify on organ donation and allocation issues that have unfortunately become controversial. We at UNOS are troubled by this current controversy, and like all of you, wish to end it and focus on doing what is needed most—working to ensure that organ donation increases and as many patients as possible have access to life saving transplants.

Donation and the current system

No discussion of organ allocation can be complete without mentioning donation. So, let me first commend HHS and Congress for their recent commitments and efforts aimed at increasing organ donation.

We face a critical shortage of donated organs in this country. The list of patients waiting to receive life saving organ transplants grows dramatically each day. Since 1988, the organ transplant waiting list has quadrupled, with nearly 61,000 men, women and children waiting for a transplant today. Yet, the number of individuals who have chosen to give the gift of life has not grown commensurately.

Many states are recognizing this problem and are implementing new laws to encourage and facilitate organ donation. For example, Pennsylvania and Maryland have passed laws that require hospitals to contact their Organ Procurement Organization (OPO) whenever a fatality occurs so that the OPO can make a preliminary decision to pursue donation of either organs or tissues. In addition, the Health Care Financing Administration recently issued a regulation requiring all hospitals participating in the Medicare system to follow similar procedures. UNOS' Board of Directors unanimously voted to support this regulation.

Obviously, the difficult decisions about organ allocation would be made infinitely easier if there were simply more organs available to those in need. Accordingly, we appreciate the Department's efforts toward this end and we stand ready to work with the Secretary and Congress on additional initiatives that will help promote organ donation. In fact, just yesterday we sent to every office on Capitol Hill some important information about organ donation including an organ donor card and we encourage you today to sign those cards and become a potential donor.

UNOS, and its predecessor organization the South-Eastern Organ Procurement Foundation (SEOPF), have been involved in human organ procurement and distribution for more than 20 years. We are a membership organization that seeks to improve transplantation through self-governance for the benefit of patients with organ failure. UNOS members represent the breadth and depth of the transplant community and are transplant centers, OPO's, patients, recipients, donor families, physicians, surgeons, scientists, health organizations and the public. UNOS was the first and has subsequently been the only private corporation to hold the Federal contract to operate the OPTN. We have now enjoyed the honor of operating the OPTN for more than 12 years.

As we exist today, UNOS, by its design, and in its role as OPTN contractor, has developed a consensus based policy-making process that is intended to continually evolve and innovate in response to technological advances, changes in donation rates and other developing circumstances. We provide a national forum for establishing sound, consensus-based medical guidelines for transplantation and the distribution of organs. Organ procurement and distribution policies are continually challenged and verified within this process to ensure the most is being made of the scarce and precious resource of donor organs. UNOS uses state-of-the-art computer technology and the best talents of the transplant community to bring the most efficient and equitable organ allocation system to patients who depend on it. The transplant community's policies are published for public comment and are ultimately reviewed and approved by HHS.

The OPTN regulation

At issue here today is the April 2, 1998 Department of Health and Human Services (HHS) Regulation governing the activities of the OPTN and laying out a framework for a new organ allocation system and process by which transplant policy is made. In testimony before a joint hearing earlier this year, my predecessor detailed UNOS' concerns with the April 2 Regulation. We have submitted detailed comments on this Regulation to HHS. I can provide both documents for the record if you would like. To summarize for you today, however, UNOS believes that: (1) the Regulation as written is subject to misunderstanding and conflicting interpretations and could potentially cause harm to patients, (2) clarification by Congress is needed to resolve the possible conflicts between the Regulation and the National Transplant Act (NOTA) (as highlighted by the AMA in its written comments to the Department), (3) the Regulation must reflect the intent of NOTA that OPTN governance and policy issues be determined by the OPTN with oversight by HHS and, (4) the Regulation should be delayed until it is rewritten to clarify the Departments intent and make other necessary changes.

Since the June 18th joint hearing, we have had five productive meetings with top HHS and HRSA officials to discuss a number of our specific concerns including the intent of some of the language which appears in the Regulation. We are pleased, for example to learn that the Department does not intend to require a "national sickest patient first" allocation system, but we continue to be concerned that this interpretation is not adequately reflected in writing within the Regulation. Our meetings thus far have been fruitful in clarifying the Department's intent and interpretation with regard to other specific aspects of the Regulation, however these discussions are not completed. UNOS firmly believes, that all clarifying interpretations must be reflected within the Regulation. Without such changes, the transplant community, patients and donor families are left wondering and worrying about fundamental components of organ procurement and allocation policy. We are hopeful that continued discussions with HHS will bring our unresolved issues to resolution.

On behalf of UNOS, thank you again for inviting us to participate in this hearing today and I would be happy to answer any of your questions.

SICKEST PATIENTS

Senator SPECTER. As I said, we are going to have to conclude at 11 o'clock or as close to that as we can. We have had others join

us on the panel. We are going to have a single round of 4 minute questions.

And let me begin with you, Dr. Busuttil. In your oral statement and writing, you have said that to give priority to sickest patients first without geographic consideration would in fact be detrimental to the goal of providing the most Americans with life-saving transplants.

I have read the statement. By the way, all statements will be made a part of the record in full. Aside from the issue of providing transplants to people who are moribund, which will not be done according to the Secretary, what is your reasoning which says that giving it to sickest patients first without geographical consideration would be detrimental to providing Americans with life-saving transplants?

Dr. BUSUTTIL. A couple of reasons, Senator. First of all, if we have no geographic considerations, organs will be flying long distances. When the organs fly long distances, they have a long ischemia time. The chances of those organs not working is increased. And that is even augmented when you put those organs in patients who are critically ill.

Senator SPECTER. Is that in fact true? I am told that with the modern technological—well, never mind what I am told.

Dr. MILLER, do you agree with that?

Dr. MILLER. Well, I do not agree, with all due respect to Ron, who has tremendous experience as well—

Senator SPECTER. Well, without respect, get to the point. Does geographical distribution pose a medical problem?

Dr. MILLER. I think in a full national system it might, but anything less than that probably would not.

Senator SPECTER. Well, how would it? That is a pretty important point. In a full national system, how would the organs be injured?

Dr. MILLER. Well, it depends on which organ you are talking about, No. 1. I think shipping—

Senator SPECTER. Which organs would be injured?

Dr. MILLER. Well, hearts could definitely be injured. So you really—you do not want to really preserve a heart more than 4 to 6 hours. And I think getting that across the country really could be detrimental—

Senator SPECTER. How many hours did you say?

Dr. MILLER. 4 to 6.

Senator SPECTER. Can any other organs be injured?

Dr. MILLER. But, you know—but the liver can oftentimes make it across the country safely. But you can probably—

Senator SPECTER. Can any other organs be injured? I want to come back to Dr. Busuttil. He is shaking his head no with livers. Any other organs injured from a national distribution?

Dr. MILLER. Probably the lung, but—

Senator SPECTER. Probably?

Dr. MILLER. The lung.

Senator SPECTER. The lung?

Dr. MILLER. Yes.

Senator SPECTER. Would all of you gentlemen give us a written answer to that question, which is a very core question?

Dr. MILLER. Sure.

Senator SPECTER. Dr. Busuttil, you were shaking your head no. Do you want—

Dr. BUSUTTIL. Well, we have looked at this.

Senator SPECTER. Excuse me. The question—I am not finished. Do you, just to sharpen the focus, do you want to disagree with Dr. Miller on the issue of livers being shipped nationally?

Dr. BUSUTTIL. Yes, sir; if you transport a liver for 1,000 miles or more, the likelihood of getting that liver into the recipient within 12 hours is not—you usually will get it in within about 12 hours.

Beyond 12 hours of ischemia time, the chances of the livers not working increases. Therefore, if you are going from coast to coast, there is a higher incidence of nonfunction of that organ. And I think every transplant surgeon would agree with that.

REMARKS OF SENATOR FAIRCLOTH

Senator SPECTER. Senator Faircloth.

Senator FAIRCLOTH. Thank you, Mr. Chairman, and thank you for holding this meeting.

How long will a heart last? I mean, it might vary from a super well heart to one that was not so well. But how long, if you take one out of a patient in New York, how quick does it have to be back in a patient in somewhere? How long? Either one.

Dr. BUSUTTIL. Well, usually, as Charlie said, usually 4 to 6 hours is what most centers will allow the ischemia time of the heart.

Senator FAIRCLOTH. Well, 4 to 6 hours does not get you very far around the country, because you have to get it back into the patient. There is more time than just the flight time.

Dr. BUSUTTIL. That is correct. That was the point I was making.

Dr. MILLER. But, you know, I looked at how long it took us to get livers in in our institution, about 1,000 different livers. And I found there was no difference in ischemia time from the ones we had just in our local area from ones that we had taken as far away as Denver, CO. There are lots of reasons—

Senator FAIRCLOTH. There was no difference in time?

Dr. MILLER. No difference, no. Because basically, if you get it in under 12 hours, it works just perfectly, actually probably 14.

Senator FAIRCLOTH. A liver.

Dr. MILLER. Yes.

Senator FAIRCLOTH. But a heart not.

Dr. MILLER. Not a heart.

Senator FAIRCLOTH. But a liver has a longer shelf life.

Dr. MILLER. Kidneys last—

Senator FAIRCLOTH. A longer shelf left. [Laughter.]

Dr. MILLER. And kidneys even longer.

Senator FAIRCLOTH. All right. I am through. Thank you.

PREPARED STATEMENT

Senator SPECTER. Thank you very much, Senator Faircloth. Your full statement will be inserted into the record at this point.

[The statement follows:]

PREPARED STATEMENT OF SENATOR LAUCH FAIRCLOTH

If ever there was an issue deserving of considerable public debate, it's the issue of our Nation's policies regarding organ donation.

We're awed by the science that allows us to take organs from one person and put them successfully into another. We've all but eliminated the earlier problems of organ rejection, thanks to the new drugs we've developed.

Science is bringing us to a point where we can grow new organs from just a few cells, or even doing successful trans-species transplants.

But as the science progresses, we find waiting lists for organs growing longer and longer. People are confused, frustrated and anguished as loved ones wait for the organ that will restore them to a healthy life.

As they wait, questions abound about our National organ allocation policies.

Why do we have different policies for different organs?

Why are the rules regarding livers different from those regarding kidneys—especially in this day of Federal Express overnight deliveries?

And we can't overlook the role money plays in getting an organ.

If you can afford to pay the fee to be on a waiting list in every part of the country, you're likely to get an organ faster. Is this fair? Obviously not.

Why are Americans in North Carolina waiting for organs when enterprising surgeons in Oklahoma are bringing in rich folks from other parts of the World for American organ transplants. Is this right?

These are the things that beg healthy public discussion and oversight, which we're doing today. Now I know that some folks feel strongly about this and feel we've waited long enough—that we need to act.

I don't disagree we need to make improvements, but we need to include everyone. Having the Department of Health and Human Services try to jam final regulations down our throats isn't going to help if they're not willing to recognize the role that Congress plays in this process.

Now I'm an organ donor. If there's anything left that someone needs, I'm happy to be a donor. We need to do all we can to increase the number of folks willing to do this. I'm glad to see that we're going to be addressing this very important subject today. Thank you.

REMARKS OF SENATOR MURRAY

Senator SPECTER. Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman, for holding this hearing on obviously a very difficult subject. I do have a statement I would like to submit for the record and some questions I would like to submit for Secretary Shalala to answer.

Let me just ask one question of the panel. I have heard a lot from surgeons. I have heard a lot from patients in my State. But I have not heard very much about the impact of the current structure or the proposed regulations on children from low income families, not necessarily those without insurance, but those who have kids with other kids at home that cannot travel from center to center. Perhaps both parents have to work.

If any of you could comment on that, I would appreciate it.

Mr. IRWIN. Senator, if I might comment on that, I think that the system can really be toughest on children, not just low income children, but all children. Being from the Pacific Northwest myself, I know that there are limited opportunities for transplantation for children in our area.

As a result, they oftentimes have to go to cities like San Francisco or Omaha, where they face long waiting lists. And unfortunately, because of the way the current system works, a pediatric organ that is found in our area would first, because of the allocation system, be offered to an adult at a local transplant center before offered to a child somewhere else, even though that child might be from our own community.

And there was an interesting report that was presented at a conference of pediatric surgeons recently that talked about how devastating on a national level that this is for children.

So this is a real problem in the system that I do not think we can ignore. And it is not just low income children; it is all children that are suffering under the system.

Senator MURRAY. Does anybody else want to comment?

Dr. PFAFF. Well, let me comment, Senator. Actually, there are an awful lot of systems that are points, particular efforts to give particular advantage to children so that children awaiting a kidney transplant have remarkable priority. So half the children are transplanted each year, as opposed to about 4½ percent of all patients who are on dialysis.

For livers and hearts, provisions have been made in each circumstance to try and hasten the pace of transplantation with greatest priority. And that has occurred through the community system. We were painted earlier as a unitarian group. In actuality, it is whole bunch of entities perhaps not too much like Congress in that it is run in a democratic fashion.

Dr. BUSUTIL. Senator Murray, I would like to make one brief comment. We have a very active pediatric transplant program. I transplant about 50 babies a year. Over one-half of those babies are indigent babies. They are either from single family parents—there is a real problem in how these people are able to take care of those babies and how we are able to get support for those families.

And clearly, it would be almost unheard of for these—they would not be able to get a transplant if they had to travel long distances away from our center.

PREPARED STATEMENT

Senator MURRAY. Thank you, Mr. Chairman. I know we are on a short timeframe.

Senator SPECTER. Thank you very much, Senator Murray.
[The statement follows:]

PREPARED STATEMENT OF SENATOR PATTY MURRAY

Today's hearing, unlike some of the hearings we have here in Congress, is truly about life or death. The issues surrounding organ procurement and allocation are by far the most difficult for us as legislators to address. We make public policy not medical decisions.

I have heard from many constituents about the new proposed regulations issued by HHS. I have heard from surgeons concerns about the transplant center at the University of Washington and I have heard from patients concerned that they will face additional delays in receiving an organ.

Because of the emotional and difficult issues surrounding current policy and the proposed changes, it has become almost impossible to charter an acceptable course for this debate.

I have some real concerns about the impact of the proposed regulations, especially in the Northwest, but I am not sure that the current structure is acceptable either. Currently, Washington state residents have a 241-day waiting period for a new liver. While this is below some regions of the country it is not a great situation.

I have read through much of the testimony of today's witnesses and am hopeful that working together we can find an acceptable structure based on fairness and equity, not politics. We need a system that is more uniformed and were everyone, rich or poor, young or old, black or white has the same chance of receiving the true gift of life.

I have supported a delay in the regulations in order to give all interested parties the opportunity to review the current structure as well as the proposed reforms called for by HHS. I also think that the additional time will give Members of Congress the opportunity to review the data and make more informed decisions based on facts, not emotions.

I thank the Chairman for scheduling this hearing and I thank the witnesses for their willingness to testify.

NATIONAL SYSTEM

Senator SPECTER. Dr. Miller, with respect to a national system, would that be helpful with respect to heart transplants?

Dr. MILLER. Again, as I stated in my opening testimony, a national system does not necessarily mean a single national list. So what you really need to—

Senator SPECTER. Well, what would the advantage be of a national system with respect to hearts, which cannot last longer than 4 to 6 hours on transplant?

Dr. MILLER. Well, I think a national system, where the country was broken up into a number of smaller regions, where the organs would be able to be transported within the framework of those—

Senator SPECTER. Well, what would the advantage then be of a national system? Would a regional system be adequate?

Dr. MILLER. Well, I think a national system can be a system of a few regions, but not 63—

Senator SPECTER. Well, what would be the advantage of having a national system? If you have a national system and you are talking about heart transplants, what would be the advantage? How big would the region and how far can you move with a heart?

Dr. MILLER. Right.

Senator SPECTER. You send these commercially? You send these by special charter? How do you send these organs?

Dr. MILLER. Well, the hearts—it varies from the organs. Hearts are usually procured by the home center. And, you know, we have flown down to Louisiana, about 1,500 miles, to get hearts. So that is a long ways. And that is within the safe procurement distance.

Senator SPECTER. 1,500 miles to Louisiana and then 1,500—and how far back? How do you do that within 4 to 6 hours?

Dr. MILLER. You only have to get it back. You go down there and you take it out and you just bring it back. And you can get—

Senator SPECTER. Why Louisiana?

Dr. MILLER. Why—

Senator SPECTER. Why do you illustrate with Louisiana? Do they have an abundance of organs?

Dr. MILLER. They may, but that is not why I did. I just—

Senator SPECTER. You just picked Louisiana at random.

Dr. MILLER. Actually, it is the one I remember going to. Maybe they do.

Senator SPECTER. Is there something special about Louisiana for organs? [Laughter.]

Dr. MILLER. There are a lot of things special about Louisiana.

Senator SPECTER. I ask that because Congressman Livingston is raising the issue on the House side.

Dr. MILLER. Right. Well, I think—

Senator SPECTER. Run me through this as to how a national system would help with heart transplants.

Dr. MILLER. Well, I think again a national system can be—it does not necessarily mean a single national list.

Senator SPECTER. Broken up into regions. Now work through a regional approach.

Dr. MILLER. So, let us see. If we want to transport 4 to 6 hours, we can fly 1,500 miles. Maybe 3 regions would do a good job. Three regions is really a national system.

Senator SPECTER. 1,500 miles?

Dr. MILLER. Let us say a 1,500 mile radius from anywhere from a donor. Just track out 1,500 miles and see who is the neediest. That could work.

Senator SPECTER. And you could get a heart in 4 hours to be on the conservative side, 1,500 miles.

Dr. MILLER. Oh yes; all you have to do is——

Senator SPECTER. Do you transport these by charter jet?

Dr. MILLER. Yes; the team is transported down and transported back by charter jet.

Now livers, there is less stringent requirements. We can—I mean, I have sent Dr. Busuttil livers.

Dr. BUSUTTIL. They never work.

Dr. MILLER. Why?

Senator SPECTER. What do they——

Dr. BUSUTTIL. The ones you send me——

Senator SPECTER. Give me the other organs. You can talk later. Give me the other organs and the timespan. What other organs are acceptable for transplants and how long will they last?

Dr. MILLER. Well, the lung is also limited, like to about 4 hours. But the liver much longer. The kidney is often flown around the country for a variety of different regions.

Senator SPECTER. How long can you have a kidney in transit?

Dr. MILLER. 24 to 36 hours.

Senator SPECTER. Any other organs?

Dr. MILLER. Pancreas I would say about 12 hours.

Senator SPECTER. Any other organs?

Dr. MILLER. We are not transplanting any other ones than that at this point.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. Well, what I would ask you gentlemen to do is to comment on this critical issue of how long the organs last and how it works.

And Mr. Irwin and Dr. Miller, how would it function, if you moved from a national system to a regional system? And what is the scientific evidence that you have as to how long the liver will last? And the same thing for Dr. Busuttil and Dr. Pfaff with a response to that.

Because if the medical science does not hold up on time, that is obviously a very, very big factor. Or with the limitations of time, what are the other advantages which would be present from a national system?

[The following are written responses to Senator Specter's questions asked at the hearing.]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

RESPONSES OF DR. CHARLES M. MILLER

At the hearing today on organ transplantation, questions were raised about the maximum viable ischemic times for each organ (i.e., the time that an organ can remain outside the human body and still be viable for transplantation). It was sug-

gested that the HHS Final Rule compromises patient outcomes by needlessly prolonging ischemic times. The opposite is true. The HHS Final Rule calls for the OPTN to develop allocation policies that meet performance criteria that specifically incorporate the consideration of factors such as the ischemic times.

Specifically, the HHS Final Rule mandates that the OPTN consider medical criteria, including ischemic times, for each type of donated organ in developing organ allocation proposals. Section 121.8(a)(3) requires that all organ allocation policies be designed using “sound medical judgment” and “to avoid wasting organs” (63 FR. 16335). In the Preamble to the Final Rule, HHS discusses at length the issue of ischemic time limits and the transportation of organs at 63 FR. 16314–16315. The essence of the HHS discussion can be summarized in this sentence from the Preamble: “The performance goals are designed to allow (and require) the OPTN to craft policies tailored to each organ transplant type that are workable, feasible, and avoid organ wastage.” Copies of the relevant portions of the Preamble are attached (Appendix A).

With respect to your inquiry on ischemic times for specific organs, transplant professionals generally agree that current, safe ischemic time limits for specific organs are as follows:

Ischemic times for specific organs

<i>Organs</i>	<i>Hours</i>		<i>Hours</i>
Hearts	4 to 6	Kidneys	24 to 36
Lungs	6 to 8	Pancreas	18 to 24
Livers	13 to 16		

For each organ, the ischemic time begins during the operation to remove the donor's organs, when blood flow to the organ is interrupted, just prior to removal from the body. The ischemic time ends when the organ has been transplanted into the recipient and blood again flows through the organ. An organ remains safe, healthy and viable when transplanted within the above times, regardless of the distance the organ travels.

I hope this has appropriately and completely addressed your questions. If you have any further questions regarding this or any other issue, please do not hesitate to call.

APPENDIX A—63 FR 16314–16315

We are reminded that there are practicalities involved, including especially transportation. The problem is not occasional cross-continental shipping from one large city to another, which is relatively straightforward. Instead, however, there can be severe logistical problems with frequent shipping of organs (often preceded by a special team that travels to retrieve the organ and return with it), or with moving organ among relatively transportation-disadvantaged areas, even within the same State. The performance goals are designed to allow (and require) the OPTN to craft policies tailored to each organ transplant type that are workable, feasible, and avoid organ wastage.

Many commenters urged that the Secretary require rational sharing of organs, without any role for geographic factors. Others urged regional sharing. We prefer the performance goal approach. Achieving the goal will certainly require greater geographic sharing and will probably require national sharing for sorry organs for patients with specified medical conditions. Indeed, regional sharing is already a prominent feature of heart allocation, and national sharing a prominent feature of kidney allocation. However, we believe that any simple formulation would inhibit the ability of the OPTN to craft the most sensible policies that achieve practical as well as ethical results, and we wish to encourage change over time as medical science and medical criteria improve. Therefore, we are at this time using the performance goal approach for all organs (with an accelerated schedule for the initial revision of policies for liver allocation).

The Secretary appreciates that there are many factors that can contribute to achieving the geographic equity goal. For example, if the Departments organ donation initiative were to achieve a high rate of success, then fewer organs would need to be shared. Improved listing criteria and medical status categories will reduce measured inequities. Nonetheless, within foreseeable parameters, we see no basis to expect that inequities can be eliminated for any major organ category without broader geographic organ sharing, on at least a broad regional basis for all patients with high levels of urgency.

We also require the OPTN to take into account key constraints on organ allocation. There are patients with urgent need for whom transplantation is futile. Organs cannot be used without an assessment of the immune system and other physical conditions of patients. Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times. Efficient management of organ allocation will sometimes dictate less transportation when the highest ranking patient can wait a day or two for the next available organ. Sound medical judgment must be exercised before a final decision on whether to transplant a particular organ into a particular patient. Our goals allow for these factors to affect transplantation outcomes. For example, current OPTN policies take into account the special medical needs of children. The Secretary endorses this approach and expects that the OPTN will continue to take these needs into account as it develops new medical criteria and allocation policies.

RESPONSES OF DR. WILLIAM W. PFAFF

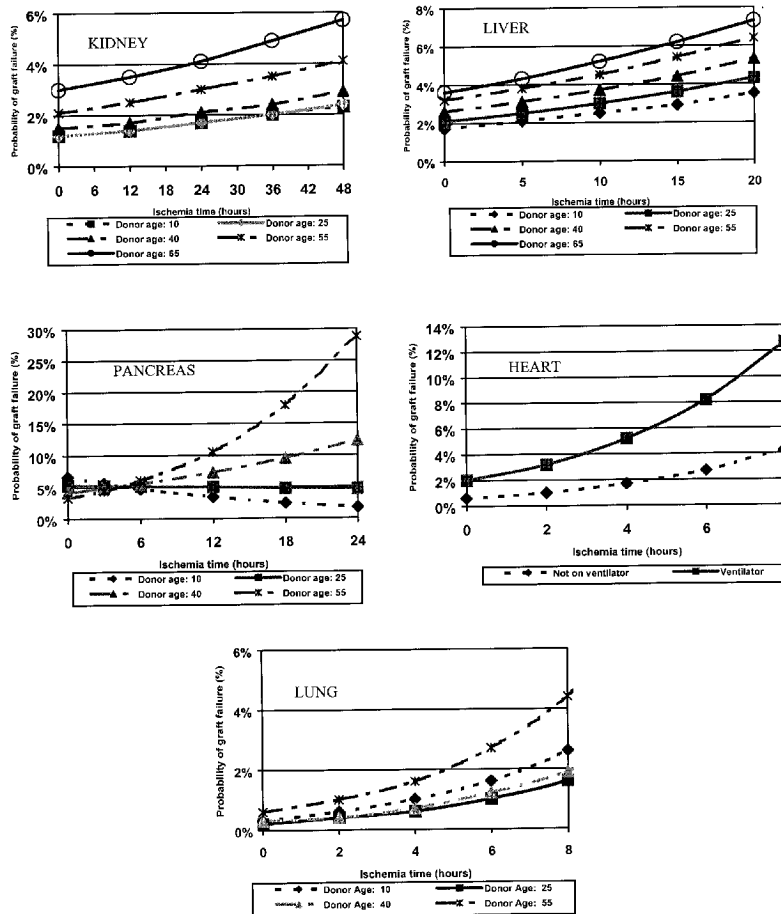
On behalf of the United Network for Organ Sharing (UNOS), I am providing you the additional information requested at your September 10, 1998, hearing on organ donation and allocation. Attached you will find the most current data available that demonstrates the probable effect of ischemic time (or time a donated organ can survive without a blood supply) on organ graft survival for kidney, liver, pancreas, heart, and lungs.

In addition to our data analysis I am also providing you with UNOS' current allocation policies for each organ. As you will undoubtedly note, these policies take into consideration the medical impact of ischemic time. You raised an important point during the hearing that needs to be emphasized in the discussion of the implementation of the April 2 regulation: a system for sharing donated organs nationally is not currently medically feasible for every organ type. The undisputed biological consequences of increased ischemic time on organ graft survival make it wholly inadequate to expect, for example, hearts or lungs to survive cross-country sharing.

As I hope you will also note from this data, while younger donor organs do indeed have stronger resistance to the effects of ischemia, the percentage of older donors has increased substantially in recent years (with the overall number of donors remaining constant). Therefore, it is fundamentally important that allocation policies particularly for livers, pancreas, kidneys and lungs recognize this factor as well.

We appreciate the opportunity to share this information with you and hope that it is useful as you consider the impact of the April 2 regulation. We would be pleased to share additional information with you or to answer any questions you might have about the data we are presenting. Thank you for your interest in this important issue.

**Effect of Ischemia Time on Probability of Graft Failure Within 1 Week
By Organ Type**



Based on UNOS OPTN/Scientific Registry data as of September 9, 1998.
Data subject to change based on future data submission and/or correction.

**THE IMPACT OF COLD ISCHEMIA TIME ON GRAFT SURVIVAL: A UNOS ANALYSIS OF OPTN
AND SCIENTIFIC REGISTRY DATA**

The impact of ischemia time (the time between organ retrieval and transplantation) on organ survival following transplantation has been well-documented (Appendix 1). Ischemic injury results from prolonged lack of blood flow and, at some point, affects organ function following transplantation. The amount of ischemia required to compromise organ function differs by organ type and for most organs, by donor age.

To quantify the effect of cold ischemia time (CIT) on graft survival using national data, we analyzed all cadaveric heart, liver, lung, kidney, and pancreas transplants performed between April 1, 1994, and December 31, 1995. The distribution of CIT for these transplants is shown in Appendix 2. The accompanying graphs show for each organ type various lengths of CIT and the associated probabilities of graft fail-

ure within the first week after transplant, as CIT has been shown to have an effect on early transplant outcomes.

Many factors determine how well and how long a graft will function after transplant. For example, the graft survival rate is affected by CIT, and for most organs, by donor age. For that reason, the accompanying data show the effect of CIT on the probability of graft failure for various donor ages. In the case of hearts, donor age did not have a significant impact on the probability of graft failure within one week. Therefore, for the heart analysis, we examined the effect of CIT on the probability of graft failure based on the recipient's respiratory status (on mechanical ventilation or not) at the time of transplant, since this factor does have an impact on graft survival. The effect of CIT shown here reflects the results of a multivariate analysis, which controlled for the effects of other donor and recipient risk factors (Appendix 3).

Organ types differ in their ability to tolerate CIT. At 6 hours of CIT, all organs except for heart and pancreas showed a 1 to 4 percent probability of failure depending upon the donor's age. In these cases, organs from older donors had a higher probability of graft failure than organs from younger donors. Pancreas transplants with as few as 6 hours of cold time already showed a 5 percent probability of failure within one week, regardless of donor age. Beyond 6 hours, pancreas transplants from older donors were more severely compromised by CIT than those from younger donors. During the time period examined in this analysis, 5 percent of pancreases were transplanted within less than 6 hours (Appendix 2).

With 6 hours of CIT, heart transplants showed a 3 to 8 percent probability of failure at one week, depending upon the ventilatory status of the patient. Because hearts are so sensitive to CIT, heart candidates are prioritized, in part, according to their distance from available donors, using a system of concentric circles, in the center of which is the donor hospital (see attached allocation policy summaries). By 8 hours of CIT, the probability of heart graft failure increased by at least 50 percent over the failure probability at 6 hours. This was also true for lungs at 8 hours. Among the lungs transplanted during the study period, fewer than 5 percent accumulated more than 8 hours of CIT. Fewer than 5 percent of hearts accumulated more than 5 hours.

Kidneys demonstrated the most tolerance to CIT. The probability of graft failure did not show a 50 percent increase until about 36 hours of CIT. Currently, only 5 percent of kidneys accrue more CIT than 36 hours. Even though kidneys can tolerate relatively long ischemia times, kidney recipients can rarely be selected at long distances from the donor, because of a laboratory test (crossmatch test) that must be done using serum from the patient and cells from the kidney donor. Often done before other organ transplants as well, this test absolutely must be done before kidney transplantation. The test rules out the possibility that the patient already has antibodies that would destroy the kidney being offered.

For livers, regardless of donor age, the probability of early failure increased by almost 25 percent by 10 hours of CIT. The probability increased by almost 50 percent by 15 hours. Under the current allocation system, which distributes livers locally first, about 35 percent of livers accrue 10–15 hours of CIT. Any system of broader sharing will increase this percentage and the associated probability of early failure.

It is important to note that an ever-increasing percentage of the donor population consists of those older than the age of 50 (see Appendix 4). In view of the finding that older donor organs are more vulnerable to ischemic injury, allocation policy revisions resulting in longer ischemia times should be undertaken with full understanding of the implications for future graft failure and retransplant rates, organ availability, and an exacerbation of the current organ shortage.

APPENDIX 1.—PARTIAL REFERENCE LIST FOR THE IMPACT OF ISCHEMIA TIME ON SURVIVAL FOLLOWING TRANSPLANTATION

Heart

Bourge, R.C., Naftel, D.C., Costanza-Nordin, M.R., Kirklin, J.K., Young, J.B., Kubo, S.H., Olivari, M.T., Kasper, E.K. Pretransplantation Risk Factors for Death after Heart Transplantation: A Multi-institutional Study. *Journal of Heart and Lung Transplantation* 12: 549–562, 1993.

Hosenpud J.D., Bennett L., Keck B., Fiore B., Boucek M., Novick R. The Registry of the International Society for Heart and Lung Transplantation: Fifteenth Official Report-1998. *Journal of Heart and Lung Transplantation* 17: 656–668, 1998.

Liver

Furukawa, H., Todo, S., Imventarza, O., Casavilla, A., Wu, Y.M., Scotti-Foglieni, C., Broznick, B., Bryant, J., Day, R., Starzl, T.E., Effect of Cold Ischemia Time on the Early Outcome of Human Hepatic Allografts Preserved with UW Solution. *Transplantation* 51: 1000-1004, 1991.

Adam, R., Sanchez, C., Astarcioglu, I., Bismuth, H., Deleterious Effect of Extended Cold Ischemia Time on the Post-transplant Outcome of Aged Livers. *Transplantation Proceedings* 27: 1181-1193, 1995.

Deschenes M., et al. Early allograft dysfunction after liver transplantation: a definition and predictors of outcome. National Institute of Diabetes and Digestive and Kidney Diseases Liver Transplantation Database. *Transplantation* 66: 302-310, 1998.

Kidney

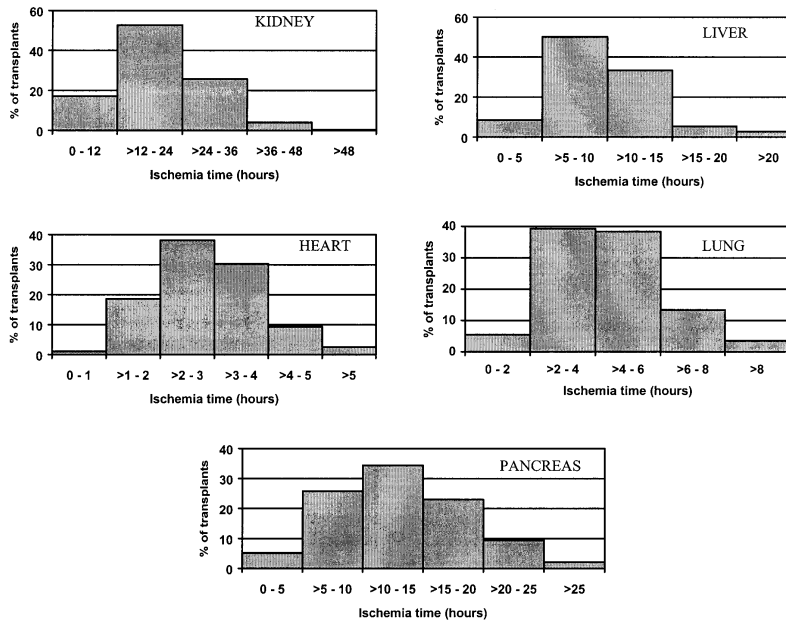
Troppmann, C., Gillingham, K.J., Benedetti, E., Almond, P.S., Gruessner, R.W.G., Najarian, J.S., Matas, A.J., Delayed Graft Function, Acute Rejection, and Outcome after Cadaver Renal Transplantation. *Transplantation* 59: 962-968, 1995.

Ojo, A.O., et al. Delayed graft function: risk factors and implications for renal allograft survival. *Transplantation* 63: 968-974, 1997.

Terasaki, P.I., et al. Significance of the donor age effect on kidney transplants. *Clin. Transplant.* 11: 366-372, 1997.

Heaf, J.G., et al. Hyperfiltration, creatinine clearance and chronic graft loss. *Clin. Transplant.* 12: 11-18, 1998.

Appendix 2. Distribution of ischemia time for cadaveric organ transplants performed between April 1, 1994, and December 31, 1995

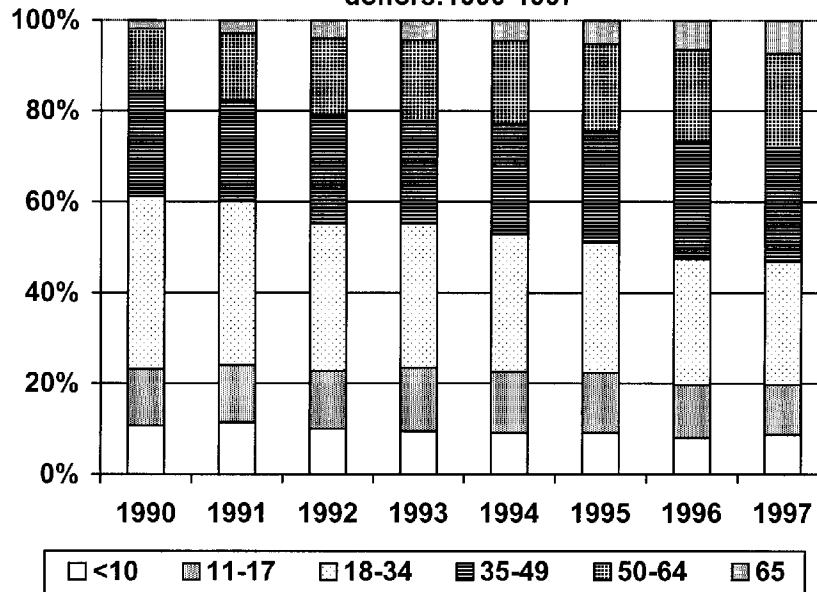


Appendix 3. Factors adjusted for in the logistic regression models, in addition to ischemia time

Kidney	Liver	Pancreas
<ul style="list-style-type: none"> • Previous transplant • Recipient age • Peak panel reactive antibody (PRA) • Waiting time • Donor age • Donor given steroids • Donor given dobutamine • Donor gender • Double organ or single organ transplant • Donor SGOT • Combination of recipient age and donor age 	<ul style="list-style-type: none"> • In ICU at transplant • Diagnosis: <ul style="list-style-type: none"> • Cholestatic liver disease/cirrhosis • Other non-cholestatic cirrhosis • Biliary atresia • ABO incompatibility • Donor age • Donor blood urea nitrogen • Donor SGPT • Donor received other pre-treatment medications • Donor race • Combination of donor gender and smoking history 	<ul style="list-style-type: none"> • Donor age • Combination of donor age and ischemia time • Donor gender • Donor blood urea nitrogen • Donor history of hypertension

Heart	Lung
<ul style="list-style-type: none"> • Recipient gender • Donor gender • Combination of recipient and donor gender • Previous heart transplant • Small volume center • Congenital diagnosis • Coronary artery disease • Recipient on VAD at transplant • Recipient on ventilator at transplant • Donor history of hypertension • Donor history of non-IV drug use 	<ul style="list-style-type: none"> • In ICU or hospitalized prior to transplant • Combination of recipient age and in ICU or hospitalized prior to transplant • Recipient age • Donor age • Combination of recipient and donor age • Donor CMV status • Diagnosis – Primary Pulmonary Hypertension • Diagnosis – Other • Donor given thyroxine • Donor history of non-IV drug use

Appendix 4. Distribution of donor age for cadaveric donors:1990-1997



BRIEF SUMMARY OF UNOS ORGAN ALLOCATION POLICIES

ORGAN DISTRIBUTION

All potential recipients of organ transplants must be registered on the UNOS computer system waiting list. Information on all cadaveric organ donors must be entered on the UNOS computer as soon as possible before organ allocation, and for kidneys within 15 hours after organ retrieval. Transplant candidates are permitted to register at more than one transplant center; however, transplant centers may not list the same patient on more than one OPO's patient waiting list. When a transplant candidate receives an organ, that patient must be removed from all organ waiting lists. With approval of the applicable UNOS Regions, appropriate UNOS committees and the Board of Directors, transplant centers and OPO's may develop inter- and intra-regional organ sharing arrangements. In addition, upon approval of the appropriate UNOS committees and the Board of Directors, a transplant center or an OPO may adopt alternative point assignments to the organ distribution criteria other than those points specified in the UNOS policies. Allocation criteria applicable to each type of organ are listed below:

KIDNEY ALLOCATION

The sharing of zero-antigen mismatched kidneys is mandatory with the exception of a simultaneous kidney-extrarenal organ transplant. Also, blood type O kidneys shall be transplanted only into blood type O patients. Kidneys shall be allocated locally first, then regionally, and then nationally to patients in descending point sequence as determined by the following criteria:

Waiting time.—A kidney transplant candidate's waiting time begins when the patient is registered on the UNOS patient waiting list. One point is assigned to the candidate waiting for the longest time with fractions of points assigned proportionately to all other patients who have waited a shorter time. For each full year of waiting time a patient accrues, an additional 1 point will be assigned to that patient.

Quality of match.—Points are assigned based on the number of mismatches between the transplant candidate's antigens and the donor's antigens. Quality of match points are assigned as follows:

- 7 points if there are no B or DR mismatches;
- 5 points if there is one B or DR mismatch;
- 2 points if there is a total of 2 mismatches at the B and DR loci.

Panel reactive antibody.—Candidates who are incompatible with 80 percent or more of a randomly selected panel are considered highly sensitized. Highly sensitized kidney transplant candidates that have a preliminary negative crossmatch with a donor are assigned 4 points.

Medical urgency.—Points are not assigned for medical urgency to candidates on a regional or national waiting list. For candidates on a local waiting list, the physician may use his/her medical judgment in assigning medical urgency points if there is only one kidney transplant center. When there is more than one local kidney transplant center, a cooperative medical decision is required prior to assignment of medical urgency points.

Pediatric patients.—Candidates who are less than 11 years old are assigned 4 additional points for kidney allocation. Candidates who are 11 years old or older but less than 18 years old are assigned 3 additional points for kidney allocation.

Donation status.—A kidney transplant candidate is assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment).

Payback of shared kidneys.—When a kidney is shared for a zero-antigen mismatch, a combined kidney-extrarenal organ transplant, or for a highly sensitized recipient, the OPO receiving the kidney shall offer through the UNOS Organ Center a kidney from the next suitable donor of the same blood type as the donor from whom the shared kidney was retrieved.

LIVER ALLOCATION

Livers shall be allocated locally first, then regionally, and then nationally to liver transplant candidates based on the following criteria:

Preliminary stratification.—For every potential liver recipient, the acceptable donor size must be determined by the responsible surgeon. The UNOS Match System only will consider potential liver recipients who are an acceptable size for a particular donor liver.

Blood type similarity points.—Liver candidates with the same blood type as the donor receive 10 points. Candidates with compatible but not identical blood types receive 5 points, and those with incompatible types do not receive any points. Blood type O transplant candidates who will accept a liver from an A2 blood type donor receive 5 points for incompatible matching. Blood type O livers shall not be transplanted to Status 2b or 3 candidates who are not a blood type O.

Waiting time.—A candidate's waiting time begins at the time the candidate is registered on the UNOS patient waiting list. Ten points are assigned to the candidate waiting for the longest period and proportionately fewer points are assigned to patients who have waited a shorter time. For example, if there are 75 candidates on the liver waiting list, the patient waiting the longest would be assigned 10 points ($75/75 \times 10$). A candidate whose rank order was 60 would be assigned 2 points ($(75 - 60)/75 \times 10 = 2$).

Status 1 and 2A liver patients.—Time of waiting will be calculated for Status 1 and Status 2A liver patients from the time the patient is listed as a Status 1 or 2A and will only include time listed as a Status 1 or 2A.

Degree of medical urgency.—Each candidate is assigned a status code which corresponds to how medically urgent it is that the candidate receive a liver transplant. Medical urgency is defined differently for adult versus pediatric candidates.

Medical urgency is assigned to adult liver transplant candidates (age greater than or equal to 18 years of age) as follows:

- Status 1.*—A candidate with fulminant liver failure with a life expectancy without a liver transplant of less than 7 days; fulminant liver failure is defined as meeting at least one of four specific medical criteria (refer to UNOS Policy 3.6 for complete details).
- Status 2A.*—A candidate who is in the hospital's critical care unit due to chronic liver failure with a life expectancy without a liver transplant of less than 7 days, and has a long-term prognosis with a successful liver transplant equivalent to that of a patient with fulminant liver failure. The patient also has a Child-Turcotte-Pugh (CTP) score greater than or equal to 10 and meets at least one of four specific medical criteria that indicate that the patient has experi-

enced a severe decompensating event (for details, refer to UNOS Policy 3.6). The CTP score is a standard scoring system used to assess severity of liver disease.

—*Status 2B.*—A candidate with a CTP score greater than or equal to 10, or a CTP score or equal to 7 and meets at least one of four specific medical criteria that indicate that the patient has experienced a severe decompensating event (for details, refer to UNOS Policy 3.6).

—*Status 3.*—Continuous medical care with a CTP score greater than or equal to 7.

—*Status 7.*—Temporarily Inactive.

Medical urgency is assigned to pediatric liver transplant candidates (age less than 18 years of age) as follows:

—*Status 1.*—A candidate with in the hospital's Intensive Care Unit (ICU) due to chronic or acute liver failure with a life expectancy without a liver transplant of less than 7 days who meets at least one of ten specific medical criteria that indicate extreme medical urgency (refer to UNOS Policy 3.6 for details).

—*Status 2B.*—A candidate meets at least one of seven specific medical criteria (refer to UNOS Policy 3.6 for details).

—*Status 3.*—A candidate who has met the inclusion criteria to be listed for pediatric liver transplantation and requires continuous medical care.

—*Status 7.*—Temporarily Inactive.

UNOS Policy also makes special provision for pediatric patients with Ornithine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I, and adult patients with Hepatocellular Carcinoma (HCC). In exceptional cases, patients who do not meet the specified medical criteria for a particular urgency status could be assigned that status upon application and justification by the transplant center to its Regional Review Board. In many regions, the Regional Review Board also reviews new patient registrations and status upgrades to determine eligibility based on UNOS Minimum Liver Patient Listing Criteria and the status code criteria listed above.

Please refer to UNOS Policy 3.6 for a complete description of all medical urgency status codes, the CTP scoring system, and specific definitions of qualifying medical events. These can be found on the UNOS Web Site at WWW.UNOS.ORG

After preliminary stratification and point assignments based on blood type similarity and time waiting, livers are offered to potential recipients in the following sequence:

Local:

- 1. Status 1 patients in descending point order.
- 2. Status 2A patients in descending point order.
- 3. Status 2B patients in descending point order.
- 4. Status 3 patients in descending point order.

Regional:

- 1. Status 1 patients in descending point order.
- 2. Status 2A patients in descending point order.
- 3. Status 2B patients in descending point order.
- 4. Status 3 patients in descending point order.

National:

- 1. Status 1 patients in descending point order.
- 2. Status 2A patients in descending point order.
- 3. Status 2B patients in descending point order.
- 4. Status 3 patients in descending point order.

ALLOCATION OF HEARTS, LUNGS, AND HEART-LUNG COMBINATIONS

Thoracic organ allocation utilizes a hierarchical system rather than a point system for prioritizing transplant candidates. Candidates are prioritized based on the following criteria:

Medical urgency.—There are two urgency categories for heart allocation. The urgent Status 1 candidate is defined as a patient who requires cardiac and/or pulmonary assistance with one or more of the following devices in place: total artificial heart, left or right ventricular assistance system, intra-aortic balloon pump, or a ventilator. If the candidate does not have one of these devices in place, he/she still may qualify as Status 1 if the candidate is located in an intensive care unit and requires inotropic agents to maintain adequate cardiac output, or the candidate is less than 6 months old. The Status 2 category includes all other candidates who do

not meet the Status 1 criteria. There are no medical urgency criteria for lung and heart-lung candidates.

ABO typing.—All blood type matches are considered equally and identical matches are not given priority over compatible matches. For organ allocation to Status 2 heart candidates and candidates awaiting a lung or heart-lung combination, candidates with a blood type that is identical to the donor have priority over candidates with compatible blood types.

Waiting time.—Except for Status 1 heart candidates, calculation of the time a patient has been waiting for a thoracic organ transplant begins at the date and time the patient is first registered as active on the UNOS patient waiting list. When waiting time is used for organ allocation, a patient with more waiting time will receive a preference over other patients who have accumulated less time within the same status category. Waiting time for Status 1 heart candidates will begin from the moment a patient is registered as a Status 1 and only include the amount of time the patient is listed as a Status 1.

Following these criteria, heart and heart-lung combinations are allocated as follows:

- For every thoracic organ donor allocated locally, the choice will be made by the transplant program whether to use the heart for an isolated heart (without lung) transplant for a Status 1 candidate, or for a combined heart-lung transplant. If the heart is used for an isolated heart transplant, the organ will be allocated first to Status 1 candidates according to length of time waiting. If the heart is not allocated to a Status 1 patient, then the organ will be allocated to other local candidates in the following sequence based on the candidate's length of time waiting:
- Heart-lung candidates with a blood type that is identical to the organ donor; then
- Heart-lung candidates with a blood type that is compatible to the organ donor; then
- Status 2 isolated heart candidates with a blood type that is identical to the organ donor; then
- Status 2 isolated heart candidates with a blood type that is compatible to the organ donor.

After local allocation, thoracic organs are allocated based upon the distance of the recipient hospital from the donor hospital. Concentric circles of 500- and 1,000-mile radii define three zones with the donor hospital as the center. Zone A extends to 500 miles, Zone B is from 500 to 1,000 miles, and Zone C is beyond 1,000 miles. Thoracic organs are allocated within each zone in the following sequence based on the candidate's length of time waiting:

- Status 1, isolated heart candidates in Zone A;
- Identical blood type heart-lung candidates in Zone A;
- Compatible blood type heart-lung candidates in Zone A;
- Status 1, isolated heart candidates in Zone B; Identical blood type heart-lung candidates followed by compatible blood type heart-lung candidates in Zones B and C;
- Status 2, identical blood type isolated heart candidates in Zone A;
- Status 2, compatible blood type isolated heart candidates in Zone A;
- Status 2, identical blood type isolated heart candidates in Zone B;
- Status 2, compatible blood type isolated heart candidates in Zone B;
- Status 1, isolated heart candidates in Zone C;
- Status 2, identical blood type isolated heart candidates in Zone C;
- Status 2, compatible blood type isolated heart candidates in Zone C.

Lungs are allocated only after the heart has been allocated. If one lung is accepted for single lung transplantation, the remaining lung will be offered for other single lung candidates in descending order on the waiting list.

Lungs are allocated to local candidates first, followed by candidates in Zone A, then to candidates in Zone B, and finally to candidates in Zone C. In each zone, lungs will be allocated to candidates who have a blood type that is identical to the donor followed by candidates with compatible blood types. Recipient selection within each group will be based on length of time waiting.

Lung candidates with idiopathic pulmonary fibrosis.—Lung transplant candidates diagnosed with idiopathic pulmonary fibrosis are assigned 90 days of additional waiting time when registered on the UNOS patient waiting list.

PANCREAS AND PANCREATIC ISLET ALLOCATION

Pancreata are allocated locally first, followed by regionally and then nationally. For local allocation, the transplant center may select recipients from candidates

awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor. Within each patient waiting list, pancreata are allocated to patients according to blood type compatibility and the length of time waiting. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted only into blood type O recipients.

If a pancreas is not allocated locally for an isolated or combined whole organ transplant, or a combined solid organ-islet transplant, the pancreas shall be allocated regionally and then nationally in the following sequence with recipient selection in each category based on blood type compatibility and length of time waiting:

- Isolated pancreas candidates with 0 A, B, DR antigen mismatches; then
- Isolated pancreas candidates with 1 A, B, DR antigen mismatches; then
- Isolated pancreas candidates with 2 A, B, DR antigen mismatches; then
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients and the kidney must be paid back; then
- Isolated pancreas candidates with 3 or more A, B, and DR antigen mismatches.

Mandatory sharing of zero-antigen mismatch pancreata.—If there is a candidate for whom there is a zero-antigen mismatch with the donor, the pancreas from that donor shall be offered to the candidate waiting for a combined kidney/pancreas transplant with a zero-antigen mismatch first locally, then regionally, and then nationally, based on time waiting, and then to a candidate waiting for an isolated pancreas transplant with a zero-antigen mismatch, first locally, then regionally, and then nationally, based on time waiting.

If a suitable recipient for a whole pancreas is not identified, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation.

At the regional and national levels, islet allocation is based on HLA matching, medical urgency, and time waiting. Three points are assigned to candidates with 0 HLA mismatches. Candidates with 1 mismatch receive 2 points. Candidates with 2 mismatches receive 1 point and candidates with 3 or more mismatches receive 0 points. The medical urgency criteria for islet allocation consist of two status categories. The higher priority Status 1 designation is limited to patients who have already received an islet transplant at least three weeks prior to the current allocation. These recipients are considered in urgent need because the typical islet recipient requires subsequent transplants involving multiple islets from additional donors within a short time in order for the procedure to be effective. Islet candidates awaiting their initial transplant are assigned to Status 2. One point is assigned to the candidate with the longest waiting time with a fraction of a point assigned to candidates who have waited a shorter time. For example, if there are 75 candidates awaiting islet transplantation, the candidate waiting the longest will receive 1 point ($75/75 \times 1 = 1$). The candidate with the 60th longest waiting time would be assigned 0.2 points ($(75 - 60)/75 \times 1 = 0.2$).

INTESTINAL ORGAN ALLOCATION

Intestinal organ transplantation may include the stomach, small and/or large intestine, or any portion of the gastro-intestinal tract as determined by the medical needs of individual patients. Following a local-regional-national hierarchy of distribution, recipient selection for an intestinal organ at each level is based on medical urgency and waiting time. Intestinal organs are allocated first to transplant candidates who are size compatible and have a blood type that is identical to that of the organ donor. These patients are followed by candidates who have a blood type that is compatible to that of the organ donor. The medical urgency criteria consist of 2 status categories. The urgent Status 1 designation includes candidates whose liver function is abnormal and/or no longer have vascular access for intravenous feeding. Candidates who do not meet these criteria are assigned to Status 2. The sequence for allocation of intestinal organs is as follows:

- Local Status 1 patients; then
- Local Status 2 patients; then
- Status 1 patients in the Host OPO's region; then
- Status 2 patients in the Host OPO's region; then
- Status 1 patients in all other regions; then
- Status 2 patients in all other regions.

ORGAN ALLOCATION TO CANDIDATES AWAITING A MULTIPLE-ORGAN TRANSPLANT

Candidates for a multiple-organ transplant where one of the required organs is a heart or liver shall be placed on the individual UNOS waiting list for each organ.

When the candidate is eligible to receive a heart or liver based upon the existing UNOS allocation policy for either organ type, or an approved variance to these policies, the second required organ shall be allocated to the multiple-organ candidate from the same donor if the donor is located within the same local organ distribution unit where the multiple-organ candidate is registered. If the multiple-organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type shall be paid back to the Host OPO from the next acceptable donor recovered by the recipient OPO.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much for being here, that concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 11:08 a.m., Thursday, September 10, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

Material Submitted Subsequent to Conclusion of Hearing

[CLERK'S NOTE.—The following statements and letter, were received subsequent to conclusion of the hearing. The statements and letter will be inserted into the record at this point.]

PREPARED STATEMENT OF THE UNIVERSITY OF PITTSBURGH MEDICAL CENTER

The University of Pittsburgh Medical Center (UPMC) respectfully submits to the Senate Appropriations Committee the following comments to evidence our general support for the Final Rule (63 FR 16296) governing the U.S. Organ Procurement and Transplantation Network (OPTN) issued by Secretary Shalala on April 2, 1998. We do not believe there should be any more delay in implementation of the Final Rule.

At the outset we must note that UPMC has advocated a position that goes further than that adopted in the Final Rule: i.e., that the Secretary should adopt specific allocation policies for donated organs. We did so based on our belief that the development of national organ allocation policy is a decision that should not be left solely to a non-governmental body. Our position was also influenced by the fact that the current OPTN contractor has not shown any inclination to respond to the evident inequities in the current national organ allocation system, as characterized in the 1994 proposed rule and as evidenced by the results of a number of analyses presented in reports by government agencies, including GAO and OIG, and by the contractor's own analyses and data.

Nevertheless, UPMC understands the position taken by the Secretary in the Final Rule, which is to allow the transplant community to exercise medical judgment within policy parameters set by the Final Rule and implemented through the OPTN contract, to develop organ allocation systems that meet specific performance guidelines.

We note that since the publication of the Final Rule, the OPTN contractor and others in the transplant community have engaged in a concerted effort to discredit the Final Rule and its performance standards by offering a "parade of horrors" that will purportedly result from implementation of the Final Rule. These false predictions contradict the views and judgments voiced by an overwhelming number of patients and patient groups, including Transplant Recipients International Organization, the American Liver Foundation, the Minority Organ and Tissue Transplantation Education Project, and the National Transplant Action Committee, which all support the Final Rule. The voices of the patients have been drowned out by the wails of protestations arising from transplant programs, transplant surgeons, and representatives of organ procurement organizations (OPO's), who have focused primarily on protecting a monopoly of donated organs which they believe belongs to them. (In fact, the National Organ Transplant Act (NOTA) was purposely written to prevent such monopolies.) Yet, it is those patients' voices that should be heard.

Of course, not all transplant programs, transplant professionals, and OPOs have taken such parochial views regarding the allocation of lifesaving donated organs. Some in the transplant community understand organs are a gift from the donors to the transplant community for the sole purpose of saving the lives of those patients who are otherwise about to die. A growing number of transplant programs and transplant surgeons recognize, notwithstanding the anti-regulation hyperbole, that the performance guidelines and other requirements of the Final Rule represent sound policy decisions, do not infringe upon the medical judgment of the transplant doctors, and most importantly, will make a more equitable system for Americans who are awaiting organ transplantation.

Liver allocation policies developed pursuant to the Final Rule will not result in an immediate and large diversion of donated livers from small and medium-sized transplant centers to a few large transplant centers such as UPMC, the University of California, and others.

At the outset, the Final Rule itself does not specify any organ allocation policy, but will simply guide the OPTN contractor to develop new allocation policies for donated livers and other donated organs over a specified time. In addition, the Final Rule requires the OPTN to consider adoption of transition procedures to be put into effect with the implementation of each new organ allocation policy “that would treat people on the national list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies.” (Regs. section 121.8(a)(5)(i)). Further, the OPTN is mandated to develop such a transition procedure to be implemented simultaneously with a revised liver allocation system. (Regs. section 121.8(a)(5)(ii)). Thus, those currently listed and waiting for organ transplants will not be treated any less favorably by a new OPTN system than under the current system.

In fact, UNOS’s newly proposed system for heart allocation contains such a “grandfather” provision. There is no “hue and cry” from UNOS or heart surgeons that the change of status definitions will harm patients on the heart waiting list at small transplant programs.

Critics argue that, over time, most of the donated livers will go to a few large transplant centers because such centers currently have the sickest patients. However, the large numbers of very sick patients currently on the waiting lists at the larger centers is a direct result of the inequities in the current allocation policy and the current long waiting times at those centers. For example, very few patients enter the liver waiting list in Status 1 or Status 2A, the most urgent categories. Most patients enter the liver waiting list as Status 3 or Status 2B. Because of the long waiting times at the larger centers (generally more than 1 year), the medical condition of the patients there eventually deteriorates until they are in the most medically urgent health status categories. Patients who enter the waiting list at transplant programs with short waiting times are able to receive a donated liver while they still are relatively healthy. In the future, under a revised allocation policy based upon the performance guidelines in the Final Rule, it can reasonably be anticipated that all patients in similar medical condition will have comparable waiting times, independent of the size of the transplant program where they are waiting for transplantation.

The important benefit that critics ignore is that under an allocation policy which complies with the Final Rule performance guidelines, no patient has an advantage over other patients based solely on location. Each new registrant will have an approximately equal opportunity to receive a donated organ as any other waiting list patient in the same status category regardless of the hospital where each patient is listed. Under such rules, it is logical that a new registrant, especially a very sick patient may well choose to stay close to home rather than travel to a larger center unless there is a compelling reason for such travel, such as insurance company requirements or special treatment capabilities at the distant center, or a high mortality rate at the local transplant center. Currently, UNOS data show that about 25 percent of all transplant recipients already travel outside their home state to be listed for transplantation.

If one removes the “organ lottery” (whereby a patient can receive a donated organ quickest) as a consideration when patients are choosing a transplant program, then patients and their physicians will presumably choose a program based on medical considerations and the needs of the patient, and when necessary, insurance company requirements. The resulting organ transplant system will thus increase patients’ options for choosing the transplant program that they and their physicians think will provide the best medical care.

A new, more equitable liver allocation policy will not cause the closure of small or “local” transplant centers due to a lack of available organs. Under a new liver allocation system developed pursuant to the performance guidelines of the Final Rule, newly registered patients at each transplant hospital will have an approximately equal opportunity to receive a compatible organ as patients in similar medical circumstances anywhere and everywhere in the country. There is no reason why any single transplant program should close if their patients wait the same time for transplantation as all other patients in the country. Each transplant program will be able to attract patients (or not attract patients) based on criteria such as: patient mortality rates; cost of transplantation; the ability of the program to treat difficult cases or certain types of liver disease; and the listing criteria of the center with regard to medically urgent patients, highly sensitized patients, or patients with little or no ability to pay.

Every transplant program will still have the advantage of “proximity” to local patients as an attraction. For example, Alabama, Arizona, Iowa, Kansas, Nebraska, New Jersey, Oklahoma, Oregon, South Carolina, and Utah are states with only one active liver transplant center, but each program performs more than thirty liver

transplants per year. Residents of those states and possibly neighboring states who require a liver transplant will still be inclined to choose such "local" centers, unless the "local" center will not accept them, or their insurance company requires them to travel to another center, or they need specialized treatment at another center. Thus, such programs are not likely to close as a result of broader geographic sharing of organs.

It is possible that a few liver transplant programs around the country may close if a liver allocation system meeting the performance guidelines in the Final Rule is implemented, if patients no longer choose to list at these programs. The transplant center, however, would continue to perform other transplants. But there is no evidence to indicate a wholesale closing of liver transplant programs. For example, according to the 1997 OPTN Annual Report, there were six liver transplant programs in the state of Louisiana in 1996, two of which regularly performed more than twenty transplants per year and four of which performed seven or less per year. One large liver program is located in New Orleans and the other is in Shreveport. It is possible that some of those four small liver transplant programs in Louisiana may close, depending on their ability to attract patients; however patients who wished to stay in-state clearly would still have the option to do so.

It is important to note that under the Final Rule medical judgments are not "being supplanted by bureaucrats," as opponents of the Rule have argued. The current system, based on consensus medical judgment within the transplant community, is to treat the "sickest first" and that concept is merely carried forward into the performance guidelines of the Final Rule. The current liver allocation policy places candidates into various medical urgency categories depending upon the severity of their illness and how long they can expect to survive without transplantation. Available organs are then allocated among those patients, with the sickest patients being the first patients offered an available, compatible donated organ. In fact, UNOS recently revised the heart allocation system to give priority to patients with life expectancy of less than one month.

Under the current liver allocation policy, however, the medical urgency of many patients is overridden by the non-medical consideration of geography. That is, a very sick patient in Dallas may die even though a compatible liver is available in Fort Worth or Oklahoma City (forty minutes away by air) because the compatible donated organ goes to a much less sick patient who is in the "local" Fort Worth or Oklahoma City area. This may happen even when the medical community agrees that the Dallas patient is more medically needy than the Fort Worth or Oklahoma City patient, and it is a prime example of the unfairness of the current liver allocation policy. The performance guidelines, therefore, correctly provide that the non-medical considerations of place of residence or place of listing shall not be major determinants of access to an organ transplant. The medical urgency status of the patient is the most important factor.

We would also note that the requirement for standardized, objective, listing criteria for transplant candidates, which will provide safeguards against potential abuses of any allocation policy, is to be developed by the transplant community. The transplant community has recognized for some time the need for standardized listing criteria, which include not only objective and standardized criteria for placing a patient on the national list, but also objective and standardized criteria for moving patients from one status to another on the list, and standardized and objective criteria for determining when patients must be removed from the list because they are too sick or otherwise not suitable for a transplant. The Final Rule requires that such criteria be developed and implemented by the OPTN, and in fact, the OPTN has already made progress in developing objective listing criteria and medical urgency categories.

The Final Rule properly permits transplant professionals to exercise their medical judgment, within certain broad non-medical parameters, to determine when a patient should properly be considered for a transplant, and when a patient should no longer be eligible to receive an organ transplant. Under the current liver allocation system, patients are often temporarily removed to Health Status 7 (inactive and not considered eligible for a transplant) or otherwise permanently removed from consideration for transplantation, because medical judgments are made that transplants for such patients would be futile. The Final Rule does not change this practice.

Organ donation should not suffer if organs are sent to seriously ill patients who are out-of-state. In a recent public opinion poll entitled "Adults' Opinions Concerning Organ Allocation Policies and Their Effects on Organ Donation," the Gallup Organization stated the following in the Summary of Survey Findings:

"A majority of adults agree with the statement, 'an organ from a donor should go to the sickest patient in the U.S. no matter where they live.' A third (33 percent) of all adults strongly agree with the statement and 50 percent agree. Asked the ex-

tent to which they agreed with the statement, 'an organ from a donor should go to a sick patient in the donor's local area rather than a sicker person elsewhere in the U.S.' most adults say they disagree—18 percent strongly disagree and 55 percent disagree."

These findings are consistent with the study results cited in the 1990 OIG report in which more than 75 percent of respondents disagreed with the statement that "donor organs should go to someone in the area where the donor lived" and a 1994 UNOS poll in which more than half of the respondents gave the highest priority to giving organs to the most critically ill patient.

The prevailing view of organ donor families can be seen in the testimony of a registered nurse at the hearings before the House Government Reform and Oversight Committee on Human Resources on April 8, 1998. In describing her decision to donate her deceased husband's organs, she wrote:

"I didn't ask or care if Jim's organs went north, south, east or west or stayed here in Wisconsin. My intent was that someone was to be given another chance to live." (p. 2)

The gift of another chance to live is the reason behind the enactment of NOTA; it is the hope of every patient on the national waiting list; and it is the focus of the performance guidelines in the Final Rule.

CONCLUSION

It is UPMC's belief that the Final Rule provides appropriate guidelines for the development of new allocation policies for donated livers and other donated organs, and that there are a number of alternative liver allocation systems that have been discussed within the transplant community over the last four years that would meet these goals and provide for a fairer system for those patients awaiting transplants. Indeed, as the Final Rule contemplated, some of these policies are being debated within the Liver and Intestine Committee of the OPTN, which has been charged with identifying those policies that meet the performance guidelines of the Final Rule.

We urge that you not delay the effective date of the Final Rule and allow the transplant community to develop the allocation policies that can provide greater benefits to the transplant patients of America.

PREPARED STATEMENT OF HOWARD M. NATHAN, DIRECTOR, DELAWARE VALLEY TRANSPLANT PROGRAM

I am Howard M. Nathan, Executive Director of the Delaware Valley Transplant Program [DVTP]. DVTP is the nonprofit organ procurement organization [OPO] serving the eastern half of Pennsylvania, southern New Jersey, and Delaware. DVTP currently serves a population of 10 million people, with nearly 3,000 of those being patients awaiting life-saving organ transplants at 12 regional transplant hospitals. DVTP consistently has been recognized as one of the nation's top performing OPOs. In 1997, DVTP was the most active OPO in the country, coordinating a national record number of organ donors (291) for any OPO service area in the United States, resulting in 917 organ transplants. I appear today to comment on DVTP's position on recent actions taken by the United States Department of Health and Human Services ("HHS") regarding organ donation and allocation.

1. DVTP Endorses the August 21, 1998 Medicare and Medicaid Conditions of Participation for Hospitals.

DVTP endorses the recently implemented Medicare and Medicaid Conditions of Participation for Hospitals, which require the referral of all patient deaths in hospitals to the area OPO, and which require the OPO or other specially trained individuals to inform families of the option to donate and request consent to donation. These rules, modeled on DVTP's experience in the eastern half of Pennsylvania, should positively impact on the underlying problem, the donor shortage. We urge Congress and HHS to maintain the Conditions of Participation that went into effect on August 21, 1998 and continue to focus efforts on increasing organ donation.

2. DVTP Opposes the Implementation of the Federal Rules for the Organ Procurement Transplantation Network (the "OPTN") Published by HHS on April 2, 1998 (the "OPTN Rules").

DVTP opposes implementing the OPTN Rules as published because those Rules vest in the Secretary of HHS the unilateral power to develop and implement policies on organ allocation. While the OPTN Rules do not dictate the content of the policies the OPTN must adopt regarding allocation and patient listing, they do grant wide latitude to the Secretary of HHS. DVTP is concerned that policy could be dictated solely by the Secretary, rather than be developed through the OPTN contractor, cur-

rently the United Network for Organ Sharing (UNOS), utilizing a process that reflects and balances the views of the transplant community at large.

Until the organ shortage that exists in this country can be fully eliminated, there will continue to be patients awaiting transplant who will die. The issue of organ allocation, and the attendant issues of who will receive organ transplants and who will not, are complicated ones that require a balanced review and consensus by those who are affected: members of the public and members of the medical community. Such a review has not yet been taken; such a consensus has not yet been reached.

DVTP supports delaying the implementation of the OPTN Rules for at least one year. This time should allow all of the constituent groups not only to reach consensus on the content of the Rules, but more importantly, to reach consensus on the content of any policies governing allocation.

3. DVTP Supports the Commitment of Additional Monies to Public Education Programs.

DVTP applauds the proposal of the U.S. Senate Appropriations Committee to commit 10 million dollars for organ donation and urges using a significant portion of those monies to support donor awareness efforts through public education programs. Financial support must be dedicated to strengthening the nation's understanding of the options families face when their loved ones die. At least five million dollars a year for at least four years should be directed to a national public education campaign such as the Coalition on Donation's campaign "Share Your Life, Share Your Decision," which was adopted by HHS for use in its national public education initiative.

Only by increasing the number of organs donated can we as a nation save the thousands of individuals who daily await lifesaving transplant operations. Initiatives such as the August 21, 1998, Conditions of Participation and national public education campaigns are critical to addressing our organ shortage crisis.

Attached are DVTP's more specific comments on the Medicare and Medicaid Conditions of Participation and the OPTN Rules.

Thank you for this opportunity to comment on the Conditions of Participation and the OPTN Rules.

PREPARED STATEMENT OF ALAN P. BROWNSTEIN, MPH, PRESIDENT AND CHIEF
EXECUTIVE OFFICER, AMERICAN LIVER FOUNDATION

Chairman Specter and Senator Harkin, thank you for giving the American Liver Foundation the opportunity to testify today on the Department of Health and Human Services' Final Rule on Organ Allocation announced by the Department on March 26, 1998.

The American Liver Foundation (ALF) is a national voluntary health organization dedicated to the prevention, treatment and cure for hepatitis and other liver diseases through research and education. ALF has 26 Chapters nationwide and provides information to 200,000 patients and families. Over 70,000 physicians, including primary care practitioners and liver specialists and scientists also receive regular information through the ALF scientific newsletter, *Liver Update*. ALF was founded 22 years ago by the American Association for the Study of Liver Diseases. In recent years ALF has provided over \$6 million to support liver research with guidance from our medical advisors.

Mr. Chairman, the Final Rule on Organ Allocation represents an exceedingly important issue and the American Liver Foundation appreciates your willingness to call this very timely hearing. Our position on the Final Rule has been developed with much thought and deliberation. Very active in our discussions have been the following physician and non-physician ALF Members: Rocco F. Andriola, Esq., Bruce R. Bacon, MD, Eugene Feingold, Ph.D., Louise M. Jacobbi, Russell H. Wiesner, MD, John Lake, MD, Ronald J. Sokol, MD, Lewis W. Teperman, MD, and John M. Vierling, MD.

The new rule for organ allocation

As stated by the Department of Health and Human Services, the rule does not prescribe specific allocation policies, but sets forth performance goals and a process by which to design and review these policies. The broad performance goals require standardized medical criteria for determining the placement of patients on waiting lists and the status of their illness. The rule also requires medical urgency and length of waiting time to be taken into account, with medical judgment the final determinant as to how organs can best be used. By creating performance goals that

will minimize waiting time disparities across the country this rule will help make the Nation's transplant system more equitable for patients.

ALF supports this new rule and notes that much of what is called for has been accomplished by UNOS serving under contract as the Organ Procurement and Transplantation Network (OPTN). More specifically, the new rule calls on the OPTN, the private sector system created by the National Organ Transplant Act of 1984, to develop revised organ allocation policies that will reduce the current geographic disparities in the amount of time patients wait for an organ. The rule also calls on the OPTN to develop uniform criteria for determining a patient's status and eligibility for placement on a waiting list. The criteria will be aimed at assuring that patients with greatest medical need will receive scarce organs based on medical judgment and common medical criteria, no matter where they live or in what transplant center they are awaiting treatment.

Liver allocation must be fair and equitable

ALF supports a system of organ allocation that most benefits patients. Allocation of organs should be based on sound medical considerations, taking into account medical urgency, practicality and sound medical judgment. This may require changing local organ procurement organization operating principles and expanding geographic areas for organ sharing. The creation of a "national list" may present risks of organ wastage and unfavorable outcomes regarding patient and graft survival.

Urgent need to explore third party conflict resolution intervention

ALF strongly believes that extensive analysis and careful consideration of any policy change must ensure that those changes improve and increase a patient's access to care and patient and graft survival. In short, the policy must benefit the patients it covers. ALF believes that the growing controversy surrounding proposed changes to OPTN policy has undermined the public's confidence and has had a negative influence on a perceived or real fairness of the system. ALF believes that this may be having an adverse effect on organ donation. For these reasons, ALF is asking that all parties, representing different points of view, come together to develop a consensus on this urgent matter. The ALF calls upon government, medical and non-profit leaders to explore the feasibility of initiating a formal conflict resolution process to assist in this matter.

The ultimate solution to the problem of scarce organs is to increase the number of donated organs

Today there are more than 55,990 people on the UNOS list waiting for a donated organ and every 18 minutes another person is added to the waiting list for organs. In contrast to the numbers on the waiting list—and about 500 people are added to the list each month—only slightly more than 19,400 Americans each year receive an organ transplant.

More resources are needed to support public-private partnerships to promote organ donor awareness. This is critical because increased organ donation will help resolve the inequities in organ allocation. Currently, slightly more than 19,400 Americans each year receive an organ transplant in contrast to the over 58,000 on the UNOS list waiting for a transplant. As a result about 4,000 people die in the United States each year while waiting for an organ transplant. This means that more than 10 people die each day while waiting for an organ. Thus, for liver transplantation in 1997, 10,000 people were on the waiting list for a liver; 4,000 received transplants; and, nearly 1,000 died while waiting.

The Health Resources and Services Administration, the Division of Transplantation has only approximately \$700,000 in its fiscal year 1998 budget for public awareness efforts to increase the rate of organ donation. The ALF believes these amounts need to be increased substantially and sustained for a decade or more to have the intended effect of changing public attitudes and behaviors to increase the rate of organ donation.

Biomedical research focused on transplantation issues should be increased to multiply the success and effectiveness of the system.

The ALF strongly believes that significant improvements in the outcome of organ transplants and significant progress to address the organ shortage can be made by expanding transplantation research at the National Institute of Health.

In the fiscal year 1997, 13 of the NIH Institutes and Centers spent \$266.8 million on transplantation research; in fiscal year 1998 the total increased to \$274.9 million, or an increase of only 3 percent. The ALF strongly recommends that the Congress increase NIH transplantation research.

CONCLUSION

Once again, we would like to thank Chairman Specter and Senator Harkin for inviting the American Liver Foundation to testify today. You have an important role to play in insuring that this debate is resolved in a timely manner. There are a number of other important areas in the Rule that are not commented on in this statement as the ALF elected to comment only on the areas considered by ALF to be of highest priority.

Mr. Chairman, attached to this testimony is the ALF position statement on the Final Rule as adopted by the ALF Board of Directors.

POSITION ON LIVER ALLOCATION: THE HHS RULE FOR ORGAN ALLOCATION
ANNOUNCED MARCH 26, 1998

The "final" rule by the Secretary of Health and Human Service calls on the Organ Procurement and Transplant Network (OPTN), the private sector system created by the National Organ Transplant Act of 1984, to develop revised organ allocation policies that will reduce the current geographic disparities in the amount of time patients wait for an organ transplant. The rule also calls on the OPTN to develop uniform criteria for determining a patient's status and eligibility for placement on the waiting list. The criteria will be aimed at assuring that patients with the greatest medical need will receive scarce organs based on medical judgment and common medical criteria, no matter where they live or in what transplant center they are awaiting treatment. ALF support this new rule, and notes that much of what is called for has been accomplished by UNOS serving under contract as the OPTN.

Liver Allocation Must be Fair and Equitable.—ALF supports a system of organ allocation that most benefits patients. Allocation of organs should be based on sound medical considerations, taking into account medical urgency, practicality and sound medical judgment. This may require changing local organ procurement organization operating principles and expanding geographic areas for organ sharing. The creation of a "national list" may present risks of organ wastage and unfavorable outcomes regarding patient and graft survival.

Urgent Need to Explore Third Party Conflict Resolution Intervention.—ALF strongly believes that extensive analysis and careful consideration of any policy change must ensure that those changes improve and increase a patient's access to care and patient and graft survival. In short, the policy must benefit the patients it covers. ALF believes that the growing controversy surrounding proposed changes to OPTN policy has undermined the public's confidence and has had a negative influence on a perceived or real fairness of the system. ALF believes that this may be having an adverse effect on organ donation. For these reasons, ALF is asking that all parties, representing different points of view, come together to develop a consensus on this urgent matter. The ALF calls upon government, medical and non-profit leaders to explore the feasibility of initiating a formal conflict resolution process to assist in this matter.

The Ultimate Solution to the Problem of Scarce Organs is to Increase the Number of Organs Available for Transplant.—More resources are needed to support public-private partnerships to promote organ donor awareness. This is critical because increased organ donation will help resolve the inequities in organ allocation. Currently, slightly more than 19,400 Americans each year receive an organ transplant in contrast to the over 58,000 on the UNOS list waiting for a transplant. As a result, about 4,000 people die in the United States each year while waiting organ transplantation. This means that 10 people die each day while waiting for an organ. Thus, for liver transplantation in 1997, 10,000 people were on the waiting list for a liver; 4,000 received transplants; and nearly 1,000 died while waiting.

Biomedical research focused on transplantation issues should be increased to multiply the success and effectiveness of this system.

The American Liver Foundation acknowledges the following individuals for the assistance they provided in preparing this position statement: Rocco F. Andriola, Esq.; John Lake, MD; Bruce R. Bacon, MD; Ronald J. Sokol, MD; Eugene Feingold, Ph.D.; Lewis W. Teperman, MD; Louise M. Jacobbi; John M. Vierling, MD; and Russell H. Wiesner, MD.

PREPARED STATEMENT OF JOSEPH L. BRAND, CHAIRMAN, THE NATIONAL KIDNEY
FOUNDATION

ORGAN ALLOCATION REGULATIONS

The National Kidney Foundation (NKF) appreciates the opportunity to provide testimony for the written record regarding the Administration's April 1998 regulations for organ allocation policy under the Organ Procurement and Transplant Network (OPTN). NKF is the nation's leading voluntary health organization dedicated to the prevention and treatment of diseases of the kidney and urinary tract and we provide assistance to individuals through programs of research and training support, patient services, and public and professional education. Our membership consists of 30,000 volunteers, including physicians, scientists, nurses, social workers, renal dietitians, kidney patients and their families, and concerned members of the lay public.

The mission of the NKF is to prevent kidney and urinary tract diseases, improve the health and well-being of individuals and families affected by these diseases, and increase the availability of all organs for transplantation. The 1998 U.S. Transplant Games, which were held in Columbus, Ohio in August, were a testament to the NKF's commitment to organ donation and transplantation. More than 1,500 athletes from all ages from across the country competed in 13 Olympic-style events, helping to celebrate the second chance at life by bringing together recipients of organ transplants of every type.

As the world's largest voluntary health organization promoting organ and tissue donation, NKF is dedicated to increasing the availability of organs to advance the health of those who need the "Gift of Life." With the transplant waiting list growing every year, new efforts are required to increase the number of organ donors. As such, we are supportive and appreciative of recent efforts by the Administration in this regard, including the requirement that hospitals that participate in Medicare and Medicaid refer all deaths to organ procurement organizations (OPO's) for potential organ donation.

Because the OPTN regulations call for such sweeping changes in organ procurement and distribution, NKF urges a delay in their implementation so as to afford the transplant community and government agencies the opportunity to fully assess their potential impact on patient outcomes, organ donation and the cost of transplantation. Furthermore, the policy goals upon which the regulations are based cannot be achieved unless uniform listing criteria are determined, accepted and implemented.

Despite many efforts of the Administration, NKF, and other organizations, the organ shortage is expected to remain constant, if not increase, as medical advances make organ transplantation an option for more individuals. Therefore, there is a crucial need to address the issue of organ supply. Nevertheless, NKF believes that the Administration's organ allocation rules for the OPTN could result in a decrease in the availability of organs for transplantation in this country. It should be noted that this conclusion was reached only after extensive consultation and input from the NKF constituency, including a survey of our 51 affiliates and discussions with our constituent councils: the Patient and Family Council, the National Donor Family Council, and the transAction Council.

Organ donation efforts are more successful in certain geographical areas than in others in part because of the effectiveness of certain OPO's and because of community spirit energized by local transplant centers. As a result of the new regulations, some transplant centers may be forced to close. This may reduce the propensity to donate organs in the parts of the United States served by those centers. Another consequence of the regulation is that there would be little incentive for OPO's to improve performance. Rather than attempting to equalize the distribution of scarce organs, greater emphasis should be placed on the evaluation and improvement of individual OPO performance. Finally, our affiliates are concerned that a policy of allocating organs to those with the greatest medical urgency could increase the number of transplant rejections and increase the need for second transplants, thus reducing the availability of organs for individuals on waiting lists who may be better recipients so far as their potential organ survival after transplantation.

National policy for organ procurement and distribution should be based upon principles of maximizing graft survival, balanced by equitable allocation. We are concerned that the effort to equalize waiting times for organs may give rise to additional inequities. For example, as noted above, if smaller transplant centers are forced to close as a result of the exportation of organs, members of lower socioeconomic groups—many of whom are minorities—may find it difficult to afford the costs associated with travel to distant transplant centers (including travel for post

transplant care). Although the goal is to “level the playing field” for transplant candidates, the new regulation would have the effect of barring certain potential transplant recipients based on ability to pay. Finally, because of the availability of dialysis as an alternative to renal transplantation, medical urgency should not be a factor in determining priority for allocation of kidneys.

We are concerned also about the impact the new allocation regulation would have on the costs of transplantation. A national allocation system would result in increased costs for either the transport of patients or the retrieval and shipment of donated organs.

We urge Congress to give careful consideration to improving access to transplantation by expanding organ donation.

PREPARED STATEMENT OF JOHN H. FITCH, DIRECTOR OF GOVERNMENT RELATIONS,
NATIONAL FUNERAL DIRECTORS ASSOCIATION

On behalf of the National Funeral Directors Association (NFDA), I am pleased to submit the following testimony for the record on the Subcommittee's September 10 hearing on Organ Donations. NFDA was founded in 1882 and is the largest funeral service organization in the world. NFDA members provide services to families across the United States. The average funeral home conducts approximately 160 services per year. Eighty-five percent of the funeral homes in America are family owned and operated businesses and have served their communities for three and four generations.

NFDA embraces the Subcommittee's commitment to increase organ donation and to oversee HHS' policies in this area. NFDA's members strongly support efforts to encourage individuals to donate healthy and usable organs. To this end, many funeral directors have publicly supported organ donation efforts sponsored by various groups and organizations.

The U.S. Department of Health and Human Services has recently issued two rules which are intended to increase the number of organ donations. Specifically, HHS has issued a final rule on the Organ Procurement and Transplantation Network (OPTN) requiring the OPTN Board to develop policies standardizing the criteria for organ transplantation. HHS has also issued a rule modifying the conditions of participation for hospitals in the Medicare and Medicaid programs regarding organ and tissue donation and transplantation. Under this rule, hospitals must implement written protocols that incorporate the following elements related to organ donation and transplantation: (1) hospitals must notify Organ Procurement Organizations (OPO's) of imminent and actual deaths; (2) OPO's must notify the family of every potential donor of its option to donate organs and/or tissue; and (3) OPO's must review death records to assure medically suitable organs were not overlooked.

Implementation of these rules and the general increase in the number of donations occurring in the United States will present challenges to the funeral service industry. NFDA would like to take this opportunity to highlight these challenges for the Subcommittee and to briefly note some of the ramifications of organ donation on family burial decisions.

While NFDA believes many families support increasing donations to help other families, NFDA encourages educational efforts to better inform families of the process and its implication for funeral arrangements. Most families are not fully aware of these implications. Family understanding of these issues is also complicated by the fact that the decision to donate organs and/or tissue is often made at a time of emotional distress. For example, it is our experience that the actual organ and tissue retrieval is often more extensive and lengthy than the family may have expected. The process of identifying a recipient for the organs, and the subsequent retrieval of organs and tissues is complex and time-consuming. Such retrievals may delay the family's funeral and burial arrangements and certain wishes of the family regarding viewing.

NFDA believes that potential organ donors and families of organ donors need to be aware of the possible implications of organ/tissue donation including the effect on embalming, the time associated with reconstructing the vascular system which is oftentimes damaged during harvesting and related damage, and the impact on viewing. To encourage these educational efforts, NFDA has initiated discussions with the American Association of Tissue Banks and the American Organ Procurement Organization. NFDA is also working with these and other relevant organizations to consider how to develop policies to address these and related issues.

In closing, NFDA believes that the disclosure of all relevant information surrounding organ donation, procurement, and harvesting as well as appropriate and ethical practices in this area are issues that should be considered as organ procure-

ment efforts are increased. We encourage the Subcommittee to review these important concerns.

Thank you in advance for your time and consideration of our comments. I look forward to working with you, your staff, and the Subcommittee on this issue.

PREPARED STATEMENT OF THE PATIENT ACCESS TO TRANSPLANTATION COALITION

This statement is submitted on behalf of the Patient Access to Transplantation (PAT) Coalition, an independent and informal coalition of transplant centers and other medical institutions which provide nationally recognized excellence in patient care. The PAT Coalition is comprised of 28 transplant centers located in 18 states across the nation.

Baylor College of Medicine	St. Luke's Hospital (Houston, TX)
Emory University	Tulane University
Henry Ford Health System	University Hospitals of Cleveland
Hermann Hospital (Houston, TX)	University of Alabama at Birmingham
Inova Health System (Fairfax, VA)	University of Florida/Shands Hospital
Jewish Hospital (Louisville, KY)	University of Kansas
Louisiana State University	University of Kentucky
Medical University of South Carolina	University of Medicine and Dentistry of
Memorial Medical Center (New Orleans, LA)	New Jersey
Methodist Hospital (Houston, TX)	University of Michigan
Ochsner Medical Institutions	University of Virginia
Ohio State University	University of Washington
Oregon Health Sciences University	University of Wisconsin at Madison
St. Louis University Hospital	Virginia Commonwealth University
	Wake Forest University

INTRODUCTION

Each year the number of individuals in need of an organ transplant grows at a far more rapid pace than the number of organ donors. The situation is now critical, with almost 60,000 patients on the waiting list nationwide. As transplant centers striving to save as many of our patients as possible, we know that the best and only solution to this crisis is to increase organ donation. Until there no longer is a shortage of organs, the transplant community will be forced to make difficult choices about how these scarce but precious resources should be allocated.

We believe that, in its April 2, 1998 final rule, the Department of Health and Human Services (HHS) removes these choices from the private-sector transplant community. It puts bureaucrats at the bedside and directs physicians and transplant centers to carry out HHS policy directives rather than following the collective medical wisdom of the transplant community. We strongly believe that these difficult and important decisions should be left, as Congress intended, to the transplant community.

Although the new HHS allocation policy may make superficial sense, it does not stand the test of reason. It focuses on the needs of the few to the detriment of the many. Remarkably, HHS admits that its chosen policy will reduce survival rates, reduce the number of patients transplanted, and increase the number of individuals on the waiting list as well as overall waiting time. Equity—defined primarily as the elimination of geographical disparities in waiting times—carries a heavy price which will be paid with patients' lives.

We are also very concerned about the impact of this policy on patient access to affordable transplantation services. The development of newer transplant centers with local and regional service areas has allowed patients from all walks of life to be transplanted. Data relied upon by HHS reveals that its allocation policy will distribute organs away from small and mid-size transplant centers to a few large centers with a high percentage of hospitalized patients. This may force some of these small and mid-size centers, which traditionally serve larger numbers of minority and low-income patients, to close.

For the sake of the 60,000 Americans who are currently waiting to receive the gift of life, we hope that Congress will ensure that this ill-advised policy does not go into effect. We urge Members to enact legislation to impose a moratorium on the regulations and to reauthorize the National Organ Transplant Act (NOTA) to clarify Congress' intent that these important medical and ethical issues be decided by the transplant community rather than HHS.

CURRENT ALLOCATION POLICY

The OPTN Contractor, the United Network for Organ Sharing (UNOS), has established various allocation systems for cadaveric kidneys, livers, thoracic organs, pancreas and intestinal organs, as well as a separate system for organs not specifically addressed. Under the current liver allocation policy (which will first be impacted by HHS' new regulations), UNOS keeps a list of every patient in the United States waiting for a transplant. When an organ becomes available, it is generally offered first to the sickest patients (ranked "Status 1") within the local Organ Procurement Organization's (OPO's) service area. If the organ cannot be used by a Status 1 patient on the local list, it is then offered to the remaining patients on the list (ranked by severity of illness as Status 1, 2A, 2B or 3). If no match for the donated organ can be found on the local list, it is then offered to patients in the multi-state OPTN region, again prioritized by severity of illness. In the absence of a regional match, the donated organ is offered to patients nationwide, with priority again given to the sickest patients.

The current policy was developed by the transplant community to achieve the maximum benefit for the maximum number of individuals in an equitable fashion. Because Status 1 patients are more likely to die than those whose needs are less medically urgent, the current system gives them first priority in obtaining local organs. However, because many patients in lower status categories also will die while waiting, and are more likely to survive surgery without requiring retransplantation, the current system next offers locally procured organs to these patients before offering them to patients within the surrounding region. When viewed as a group, transplant candidates are best served by a system which ensures the highest survival rates possible. This reduces the number of transplants which fail and require retransplantation, thereby denying another patient the chance for a transplant because there simply are not enough organs available for everyone on the waiting list.

SUMMARY OF THE HHS FINAL RULE

The final rule establishes three broad "performance goals to be achieved by the OPTN" in developing organ allocation policy. See 63 Fed. Reg. 16296 (1998) (to be codified at 42 U.S.C. part 121). The performance goals require the OPTN to establish: (1) minimum listing criteria to be used by transplant centers in determining whether a patient is suitable to be listed for a transplant; (2) status categories based on "objective medical criteria to be used nationwide in determining the medical status of those awaiting transplantation"; and (3) equitable allocation policies "that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment," and direct organs "so as to equalize waiting times, especially for those with greatest medical need." *Id.* at 16296-7.

PROBLEMS WITH HHS' ORGAN ALLOCATION POLICY

1. The policy places bureaucrats at patients' bedside

Although we recognize that HHS has oversight responsibility for the OPTN under NOTA, we believe that a direct, substantive role for the Department in developing organ allocation policies conflicts with both the letter and the spirit of the law. Under NOTA, Congress established the OPTN as a private-sector entity which, under contract with the government, assists organ procurement organizations in the equitable, nationwide distribution of organs among transplant patients. See 42 U.S.C. section 274(b)(2)(D).

Seizing on the words "nationwide" and "equitable," HHS goes far beyond its oversight role to mandate the establishment of organ allocation policy. Both the preamble and the text of the rule clearly evidence the agency's policymaking agenda. See 63 Fed. Reg. at 16311 ("[T]he OPTN must be primarily responsible for * * * developing equitable allocation policies that reflect the Secretary's policies, as expressed in this regulation."); *id.* at 16334 ("[T]he Secretary may * * * direct the OPTN to adopt a policy; or, may develop a policy that the OPTN must follow.");

The "discretion" granted by HHS is illusory. It is as if the agency is telling the OPTN to bake a chocolate cake, but allowing it to pick the recipe. Do federal policymakers really know better than transplant physicians and surgeons what is best for their patients? We think not—and strongly believe that these issues should be left, as Congress intended, to the transplant community representatives, including patients, who comprise the OPTN.

2. It will reduce survival rates and the number of individuals transplanted

When asked during a national conference call whether the new policy would yield the greatest benefit for the greatest number of patients, HRSA Administrator Dr. Claude Fox admitted that the new rule favors equity over utility. Indeed, the preamble to the rule states that survival rates will decrease with priority to the most urgent patients. *Id.* at 16325. Moreover, HHS explicitly recognizes that transplanting sicker patients will result in additional retransplantations because very sick patients are more likely to experience graft rejection. *Id.* This means that fewer individuals would be transplanted under the new policy.

The HHS policy appears to be based on the erroneous assumption that only hospitalized patients are sick enough to require transplantation. Although not hospitalized, many patients on the waiting list are homebound or bedridden. They are extremely sick, and getting sicker. Why should the government force them to wait until they are as sick as possible before they can receive a transplant? Indeed, of the 953 patients who died last year while waiting for a liver transplant, almost 60 percent were not hospitalized.

Rather than seeking to benefit transplant candidates as a group, HHS looks only at the interests of the most desperately ill patients. In so doing, the agency fails to consider the needs of the vast majority of patients waiting for organ transplants, thereby sentencing them to lower survival chances and more time on the waiting list.

3. The HHS policy will increase the number of patients on the waiting list, as well as waiting times

HHS mandates the OPTN to implement new organ allocation policies “to equalize waiting times, especially for those with greatest medical needs.” 63 Fed. Reg. at 16297. However, there is little regional variation in waiting times for Status 1 and Status 2 patients—a fact which Administrator Fox admitted during a March 26 HRSA-sponsored conference call.

It is true that the length of time that lower-status patients spend on waiting lists may vary greatly from region to region, and even within regions. However, HHS admits that waiting time variations are not reliable indicators of medical status since aggressive listing and accelerating hospitalization may artificially inflate patient waiting times and status. *Id.*, at 16311–12. Indeed, the Department admits that “current measures of waiting time disparities are weak because the lack of listing standards does not create uniform, status-related measures.” *Id.*, at 16327. Yet, eliminating these disparities is the hallmark of its proposed organ allocation policy.

It is also important to note that other factors, such as local organ donation rates, influence how long patients must wait to receive a donor organ. A recent UNOS study (McBride, et al., 1997) found that the two OPTN regions with the longest waiting times for less urgent patients had the highest ratios of patients waiting to the number of organs donated and transplanted. HHS itself admits that there are “great disparities” in the production of donor organs and that “the productivity of the local OPO directly impacts the number of transplants done in the OPO service area.” 63 Fed. Reg. at 16314.

The fundamental flaw underlying the Secretary’s approach is that it equates waiting time equality with equity. We strongly disagree. It is not equitable to take organs from regions that have successfully reduced waiting times through effective, locally-based procurement programs and give them to regions with longer-than-average waiting times.

Moreover, because geographical disparities exist only with respect to patients in less medically urgent status categories, a “sickest first” policy will only reduce disparities by forcing patients in some regions to wait longer as organs that would have been offered to them are transported to patients in other regions. Data relied on by the Secretary indicates that broader sharing will only “equalize” waiting times by forcing patients in some regions to wait up to 82 days longer for transplants to reduce waiting times in other regions by, at most, 8 days. 63 Fed. Reg. at 16327 (Table 12). In fact, HHS admits that overall patient waiting time—and therefore the number of individuals on the waiting list—will actually increase under the new allocation scheme. *Id.* at 16324–25.

While organs remain scarce, as is currently but unfortunately the case, allocation policy must take into account considerations of utility as well as equity. The new policy promulgated by HHS values “equity,” defined according to waiting times, without regard to utility, thereby prolonging waiting times, decreasing the efficacy of transplants and wasting valuable organs.

4. The HHS policy will impair patient access to transplantation services, especially for low-income and minority recipients

Lack of access to organs may drive some regional transplant centers out of business, inflicting a fundamental blow to patient access. Data cited in the preamble to the rule indicates that large centers would perform 30 percent more transplants under the new allocation scheme, while small and mid-size centers will experience 19 percent and 25 percent reductions, respectively. *Id.* at 16331 (Table 15). Our research suggests that the impact on small and mid-size centers may be even more severe. If these centers close, patients will be forced to travel longer distances at greater expense, and will be separated from their family members when they most need them.

The preamble concludes, without citing any supporting evidence, that “this concern over local access and increased travel only affects a small number of patients.” *Id.* at 16303. However, according to UNOS data, 70 percent of the patients who received liver transplants in 1996 were transplanted at centers in the OPO service area in which they resided.

Because Medicaid patients often are unable to obtain transplants outside their home states, they will be sharply disadvantaged under the Secretary’s national allocation policy. The preamble to the rule brushes off the arguments that higher travel costs and lack of health insurance will effectively exclude low-income individuals from the opportunity to receive an organ, labeling these concerns as “speculative.” *Id.* at 16303. However, UNOS data indicates that almost one in five kidney and liver transplant candidates nationwide are on Medicaid.

A new allocation policy which could eliminate access to financing for one in five transplant candidates certainly does not seem equitable.

Many local and regional centers have been serving significantly higher-than-average proportions of minority patients. UNOS data regarding the percentage of minority patients served by several OPOs is illustrative:

Mississippi: 82.4 percent and 30.8 percent African-American kidney and heart recipients, respectively.

New Mexico: 72.7 percent minority liver recipients and 70.9 percent minority kidney recipients.

South Carolina: Kidney recipients were 63.8 percent minority and 56.9 percent African American, while 41.7 percent of heart recipients were minorities.

By contrast, one of the major centers which supports the HHS rule performed only 7.3 percent of its liver transplants on minorities in 1996 (compared to the national average of 23.1 percent), and just 16.4 percent of its kidney recipients were minorities (versus 44.9 percent nationally). We are extremely concerned that the HHS policy would impair minority access to transplant services by shifting organs away from regional centers to a few large national centers which historically have served fewer minority patients.

5. The HHS policy will harm local organ donation efforts

The establishment of transplant programs serving local, state and regional areas has resulted in a marked increase in the total number of annual transplants in the United States. We firmly believe that the presence of a transplant program in a community or state provides a context and a focus for efforts to increase organ donation. Indeed, if centers are forced to close, their transplant teams will no longer be available to recover organs in the surrounding area, further hurting donation efforts.

HHS contends that it has seen “no credible evidence that local performance encourages donation.” 63 Fed. Reg. at 16304. However, this ignores the testimony of numerous expert witnesses who expressed this sentiment to HHS during its December 1996 public hearing—as well as the opinion of HHS’ own hearing chairman. After the hearing, Assistant Secretary for Health Phil Lee stated on national television that “when you have a local area with a local transplant center that vigorously educates the public in the area * * * you have a higher level of donation. That’s what we were told in the hearings.”

The public relations efforts mounted in support of the HHS rule contend that donated organs are a “national resource” subject to federal regulations and control. However, organ donation occurs locally, not nationally, and involves donor families, physicians, hospitals and organ procurement organizations, all working closely together within a local setting.

We are concerned that the “nationalization” of donated organs would, over time, undermine these relationships and reduce the incentives for vigorous, community-based efforts to increase organ donations. Rather than micromanaging organ allocation, HHS should be seeking to increase organ donation through education and legislative initiatives. Only by increasing the number of families who consent to donate

their loved ones' organs can we eliminate the shortage now forcing us to make these difficult allocation decisions.

LETTER FROM SENATOR DANIEL K. INOUE AND SENATOR DANIEL K. AKAKA

U.S. SENATE,
Washington, DC, June 17, 1998.

Hon. BILL FRIST,
Chairman, Subcommittee on Public Health and Safety, Committee on Labor and Human Resources, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: This letter is in response to Secretary Shalala's proposed final ruling on organ donation and transplantation. We applaud the Secretary's intent to increase equity among transplant candidates. However, there may be circumstances where geographic areas are unable to comply with the ruling or where compliance would cause significant hardship to a patient population. Therefore, we encourage the Congress to ensure that the Organ Procurement and Transplantation Network (OPTN) includes a mechanism for exemption from the final ruling.

The final rule emphasizes the importance of both maintaining high quality of organs to be transplanted and reducing organ wastage. Unlike any other transplant center in the United States, because of Hawaii's geographical isolation, it would be nearly impossible for us to comply with the rules. Organs would have to travel at least 2,300 miles or 5 to 6 hours just to get to the west coast. These figures do not include travel time to and from airports, flight availability, connecting flights to other cities, differing time zones, or unforeseen delays. It should be noted that times would be further increased if the organs were allocated to another area of the United States.

In a recent Honolulu case (May 2, 1998), the heart, kidneys, liver, and pancreas were recovered from a 29-year-old female. The pancreas was placed for transplant in Sacramento, California, and the organs shipped to the airport in a timely manner. Unfortunately, due to mechanical difficulty, the flight was delayed. Alternate transportation, including a private charter, was not available and, ultimately, the pancreas was wasted. It should also be noted that there are no flights leaving Hawaii after 10:40 p.m. Organs recovered late in the day could not be shipped until the next morning, adding significantly to ischemic time. Additionally, organs being allocated to Hawaii's sickest patients might also end up with unnecessary increases in ischemic times due to the flight arrangements from the mainland to the Hawaiian islands. This would dramatically reduce the quality of organs allocated to our transplant recipients to the point of endangering their lives.

We believe that Hawaii's transplant candidates would suffer tremendous hardship under the proposed ruling. If organs are allocated to the sickest patients first, the viability of our sole transplant center is at risk, eliminating reasonable access to treatment for many Hawaii residents related to their inability to travel long distances and the associated financial hardship. Thus, the ruling will unintentionally result in the creation of a two-tiered health care system, with transplantation only for the wealthy. These patients will also lose their support system during their extended treatment and recovery period. Many patients report that they cannot travel to the mainland and will then choose not to be listed as transplant candidates.

Last, Hawaii's population includes significant numbers of people of Asian and Pacific Island descent, as well as an indigenous culture. This population provides unique opportunities and challenges for the health care delivery system. We are a culturally diverse population on a small group of islands, and we maintain strong bonds to family and friends. Traditional beliefs surrounding medical care and end-of-life practices all influence participation in "western" medical care, as well as attitudes toward donation. While national surveys may predict no decrease in donation if organs are to be shared nationally, when offered the option of donation, most of our families ask where the organs will be used. To promote organ donation in Hawaii, we need to be able to inform these families that they are providing for their community.

For these reasons, we encourage the Congress to ensure that the OPTN includes a mechanism for exemptions to the final ruling.

Sincerely,

DANIEL K. INOUE,

U.S. Senator.

DANIEL K. AKAKA,

U.S. Senator.

ORGAN DONATIONS

SATURDAY, SEPTEMBER 12, 1998

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Scranton, PA.

The subcommittee met at 10:20 a.m., at the Lackawanna County Courthouse, Scranton, PA, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

NONDEPARTMENTAL WITNESSES

STATEMENT OF HON. ROBERT P. CASEY, FORMER GOVERNOR OF THE COMMONWEALTH OF PENNSYLVANIA

OPENING REMARKS OF SENATOR SPECTER

Senator SPECTER. Good morning ladies and gentlemen. We will now convene the field hearing for the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education. One of the critical issues facing the Congress in its current session is the issue of how to deal with organ transplants, a very important subject which really means life or death for so many Americans who need an organ transplant.

The Department of Health and Human Services has promulgated regulations which would establish a national system on the basis of need and there has been an effort made in the House of Representatives to delay the implementation of this regulation in order to allow the localities which have a different system for organ transplants to take effect.

We are privileged this morning to have the distinguished former Governor of the Commonwealth, the Honorable Robert P. Casey, as a witness to testify. I have known Governor Casey for many many years going back to 1966. We have served together and apart as public officials. Governor Casey has special insights into this very important issue because he has been the recipient of a double transplant.

On a personal note, the Governor had his operation on June 14, 1993, which coincidentally was the same day that I had brain surgery. Governor Casey was in the hospital at Pittsburgh and I was in the hospital in Philadelphia. The next day the Philadelphia Daily News had a front page picture of Governor Casey looking in one direction and me looking in the other direction. So we were

sort of facing each other on the separate pictures. The big headline said, "anguish." The newspaper relayed the stories about how we both had very serious operations on the same day. As soon as the word reached Harrisburg, governmental officials suspended all operations. I am not sure out of concern for Bob Casey and Arlen Specter as much as that of concern to figure out who would replace the Governor and who would replace the Senator, who would replace the man who replaced the Senator, who would replace the man who replaced the Governor. It is a complex issue of domino falling which is not typical and so it is understandable. Governor Casey and I were laughing about that a few weeks ago when I had occasion to visit him in his home here in Scranton.

SUMMARY STATEMENT OF HON. ROBERT CASEY

Well, Governor, we welcome you here. We understand that it is an easier trip for me to come to Scranton than it is for you to come to Washington. I had the opportunity to attend the Race for the Cure, incidentally, for a few minutes. So we are just a couple of minutes late in starting. But I am delighted to see you looking so well. I thank you for offering your insights and testimony on this very important issue of public concern. The floor is yours, Governor.

Mr. CASEY. Thank you very much, Senator Specter. I appreciate your coming to Scranton to this hearing and giving me the opportunity to share my thoughts on the new organ allocation and donation rules issued by Secretary Donna Shalala.

And I speak not just for myself but for those others who will be here today, other transplant recipients. Robert Solfanelli whom we met and there was a wonderful story that had a very happy ending, unlike many of these stories which do not have happy endings. And I will talk about that in a few minutes. And Mrs. Lecrone who is also an organ recipient and will testify as well.

I will start by saying that my purpose in coming today is to urge you to support the regulation issued by Secretary Shalala and move toward its implementation as soon as possible. It is important there not be any delay. I know that there is opposition in the House of Representatives and some of the States to the implementation, but there is also a collateral move to delay the implementation.

We know that the first priority on the regs is liver in terms of the chronology of how this will work out. But I would say that because 10 people die everyday because they cannot get organs. And, in many cases, due to the current inequitable allocation policy, which I will address in a minute, every day we delay means more people will have to face death because they cannot get an organ. So I hope that the committee will bear that in mind in weighing the course that you are going to take with respect to this very, very important matter.

Obviously, those of us who have been through this experience and our families have a special, very personal attitude toward it because it resulted in the saving of our lives. And, of course, each transplant recipient has a story. Now, my story is fairly well known. On June 14, as you pointed out, the same day that you were hospitalized, I received a heart and a liver transplant at the

University of Pittsburgh Medical Center. A very rare procedure, one that has been done just a few times in this country. And it was very risky but it was the only alternative I had to save my life. It was made possible by transplant pioneer Dr. Thomas Starzl, University of Pittsburgh Medical Center.

The way it developed was incredibly unique, I think. In a chance conversation I mentioned my illness and he said he could treat me with a liver transplant. And I had been 2 years into this illness and I had been told that there was no cure and no treatment. When it came time for me to face this issue, I was incredibly blessed by the generosity of a woman in Monessen, PA. Her name is Frances Lucas, whose son had been killed, by a man in a case of mistaken identity, in her own front yard.

Beaten senseless, never regained consciousness, 34 years of age, an African-American young man who had been subject to all the travails and difficulties of modern life. And his life was taken and mine was saved because of the generosity of this woman who had lost another son to violence, her older son, Eugene, shot in the back. So two sons lost to violence. And the man whose organs I carry in my body today, William Michael Lucas, a 34-year-old young man from Monessen, PA, is the reason why I am able to come to this table and talk this morning.

You know, we have all heard the Biblical expression, "greater love than this no man hath than a man lay down his life for a friend." Well, I was saved by strangers, not friends, people I never met. This incredibly generous woman whose son had just been taken from her by violence, you know, she could have said, well, do not bother me. I am grieving. My son is dead. But she did not say that. She said, my son had a good heart and it is right that someone else ought to have it.

So if you change that Biblical quotation and just substitute one word, "greater love than this no man hath than a man lay down his life for a stranger," how much more power. I was saved by strangers; a 34-year-old African-American young man, his mother; a surgical team at the University of Pittsburgh from all over the world, Japan; a Chinese-American; the Vietnamese doctor; a doctor from Ecuador; a doctor who was an American citizen who grew up and was born in Russia, his father was a diplomat, Dr. John Armitage; seven of them. And they saved my life.

And just parenthetically, when people talk about the immigration rules, we have got to keep certain people out of this country. That strikes a very personal chord with me. I think the greatest thing about this country is its diversity. And there you had my body on that table, there because of the Lucas family, being saved by seven surgeons, including an American surgeon from Nashville, people I had never met before, and they saved my life.

And my life was saved because at that point in time there was a rule, a regulation which said that we have a separate waiting list in the Pittsburgh region for multiple organ recipients. There was a separate list for heart and liver. It is such a rare procedure, there has possibly only been a few done since I had mine done, maybe a handful. I read in the Inquirer some months ago, the first one was done in Philadelphia about a year ago, heart/liver in Philadelphia.

When I went to Pitt, University of Pittsburgh, they were not doing them anyplace in the country. If I had not gone to that institution and met that doctor, Doctor Starzl, there would have been no hope for me. So I mention these details because every transplant recipient has a story, a very personal story. And there is nothing more real than what we are talking about here today.

I mean, you and I have considered all public issues of great moment, great complexity, great importance to the country. But none is more real than this one. I mean, this brings you face to face with the essence of life, what life is all about, the value of life and the fragility of life. And that is why it is so important. These regulations have the awesome power to say you shall live and you shall die. And that is the effect of what we are talking about here today.

It is essential that these rules be fair and open and understood and uniform and communicated to people who are facing these decisions. The present system is a patchwork quilt, as you know, from State to State or region to region, and we have regions, as you know, for allocation of organs. But from region to region, different waiting lists, different criteria for getting on the list, different criteria for determining medical status with respect to the urgency of the need for the organ. And it is all different. And you have got these poor people who cannot afford it, scouring every last avenue where they can find a transplant center where the waiting list is shorter so they can have a chance to live. And that is not right. It is not right.

As the current regulations mandate that the primary factor is the geographic location of where the organ is developed or where the organ originates. And that is as arbitrary as it can be. The defense for that position, I know it is couched in very idealistic terms. But I have to tell you, and I talk to people every week from all over the country, several people every week on the telephone. I call them, they call me and we talk.

It is my belief that this geographic limitation, if you will, is dictated by economic necessity from the point of view of transplant centers, small centers. You cannot transplant organs if you do not have organs. And so there is this parochial turf battle, if you will, in which the organs are first given to people in the locality. And I know you have testimony and you know that so many people go out of State for their transplants, an average of 25 percent. You heard testimony recently, I understand, in New Jersey, 64 percent of the people leave New Jersey and go to other States. And so the geographic rule in New Jersey can work against New Jersey citizens.

Talk about the law of unintended consequences. You can have a transplant recipient go from Newark to Philadelphia and have an organ that shows up in New Jersey a week later and because of this rule the Jersey resident in Philadelphia can be at death's door but that organ will go to someone in New Jersey, in all likelihood, who is less sick than the New Jersey resident in Philadelphia across the river. Now, that does not make any sense. The priority ought to hinge on medical necessity and sound medical judgment. I know the rules say that the geography can be taken into account but now it is the No. 1 factor.

And so much has happened since 1984 when the National Organ Transplant Act was put into effect, as you know. The ischemic life of organs is much longer now. They can transport them longer distances. You can even probably go coast to coast, I would think, with most organs, although it is not uniform.

But I am advocating today a position in which the sickest people get the priority based on medical need and medical urgency. You know, it is a very simple illustration. If you come on an accident scene and there are five people injured, two of them critical and three less so, you do not take the ones that are not badly injured to the hospital first. You take the critical ones first. That is what medical ethics requires. The American Medical Association has said that, that it is unethical to prohibit the transportation of organs unless the life of the organ will not permit the transportation. But otherwise it is unethical. So what we are advocating today is not only morally right but it is right in terms of the ethics of the profession.

When I had my transplant, first I met with my doctors and said, look, there are certain rules that apply to this procedure. And I want you to all look me right in the eye and tell me that you are going to follow the rules in my case to the letter. OK. We got that clear? And they did, to the letter. I mean, I want fairness for myself and I want fairness for everybody else, too. And it is high time for this system is changed so that fairness was the rule of the day. Fairness predicated on medical urgency and medical necessity, not to arbitrary accident of where the person lives or where the person is listed for transplant or where the organ originated. That is a self-serving rule designed to protect parochial interests.

In this system, the patient should be first, not transplant center, not transplant doctors, not the cash flow of some new transplant center that needs organs to survive. That is not the criteria. They are important considerations. I do not diminish them. But the No. 1 priority has got to be what is best for the patient. How can we save more lives? How can we make the system more fair and demonstratively fair so that people can look at it and say, this is a fair system, I want to donate my organs to that system because it will be handled correctly?

And studies have been made that show that people do not care about geography when they donate organs. They do it as a living memory of their loved ones and to save the life of the recipient. And, you know, every organ that is donated can save numerous lives. I will read something to you in a minute that touches on that. But fairness is something that has got to be the touchstone. Equal opportunity, and allocation policies which put a patient's location and the origin of the donated organ on a higher priority than the patient's medical need and medical status are simply wrong. They are unjust, and in my judgment, they ought to be changed. It has got to be fair to all patients, no matter where they are listed, no matter where they live.

On the average, 25 percent of all transplant patients travel outside of their home States for their transplant medical care. That is the first point I want to make. Allocation based on medical need and urgency.

The second point goes to the question of notification when a person is deceased, so there can be a dialog between the organ procurement organization in that local area and the family of the decedent. And of course, it is obviously very helpful if the decedent, during his or her lifetime, indicates a desire to have the organs donated. That simplifies the process considerably.

But, as you know, in 1995 in Pennsylvania I signed Act 102 which requires that the organ procurement organization be notified of the death of the decedent to give professionals, trained people, an opportunity to consult with the family and explain to the family the importance of this. And it is a very, very difficult and sensitive thing because they are in bereavement. They are in shock. But people in their infinite goodness can rise above their grief and their shock and the tendency we all have to be selfish and be generous. And believe me, that is God's work in a very literal sense.

So the organ notification law went into effect in Pennsylvania in 1995. In the southeastern part of our State under the leadership of Howard Nathan, whom you know, and who has worked very hard in this area, one of the representatives here today, organ donation in the eastern half of the State in the last 3 years has increased 40 percent. Transplantation has increased 50 percent. Now, when you translate that into organs and people, you are talking about hundreds of lives being saved just in the eastern half of one State. Imagine if that rule were in effect nationwide. It is fair to say that thousands of people would be saved.

For the life of me, I cannot understand why the House of Representatives, which I understand has been dealt this case, put a rider on this appropriation bill that you have before your committee which struck that notification provision. What reason can be imagined for such a change? Why would anyone want to do that? I mean, it just defies comprehension because it is so demonstratively efficacious and effective. It does not cost any money. It is a simple thing to do. But it is working in Pennsylvania. And it is being modeled and followed in at least four other States in the country.

And as you know, the language in this regulation, there was a White House ceremony not too long ago where the new allocation policy of the Federal Government under Secretary Shalala's direction was announced and they said specifically in that proceeding in that public event that they were following the model of Pennsylvania law.

So I mean, empirically it is working. And it will work nationwide. And that is the second point that I would make. We now have something like 55,000 people each year who receive these organs. I think something like 4,000 die because they cannot get organs, 10 every day. And I think that is something, I think, that has to command the attention of all of us.

And by the way, if you are comparing the purposes, Howard Nathan's group advises me that while organ donation in the eastern half of Pennsylvania was going up 40 percent, the rest of the country went up 6 percent. So you get some sense of the magnitude of the difference.

ORGAN DONOR FAMILIES

I served for a year as the president of an organization called Transplant Recipients International Organization [TRIO]. This is the only organization, to my knowledge, in this country which is dedicated exclusively to the advocacy of patients, transplant patients, those on waiting lists, organ donor families who have donated organs. And after all the organ donor families are the ones that make it all possible. But this organization called TRIO advocates on behalf of all of them, a nonprofit organization, not for transplant centers, not for transplant physicians, not for organ procurement organizations.

We have a system now, which you know, an organization called the United Network on Organ Sharing [UNOS]. Well, it is delegated by the Congress after the 1984 National Organ Transplant Act, with the responsibility for running this system. It is a private organization funded with some public money but also funded with the fees that patients pay to get on the transplant list. It costs something like \$357 to get on the transplant list. Those fees, as you know, go to UNOS.

This organization has enormous power. No one votes for them. There is very little, as far as I can see, accountability. And I want to urge you in the strongest possible terms to raise the Congress to be active in its oversight of this organization. It has enormous power. I am told that hospitals cannot get reimbursed unless they are approved by UNOS. So they have, in effect, rulemaking and legislative power.

Oversight is badly needed because all of the members of that organization, and there are some wonderful people in the organization, but they have their own interests, their own professional and economic interests, which has to be taken into account in deciding on the fairness of what they do. So oversight is essential.

I would like to read something from the TRIO newsletter, which came out this month, in September. And I quote, "more than 60,000 Americans are awaiting transplants." This number is climbing weekly. Meanwhile, there are only about 5,000 donors annually and this number is stagnant. We have this situation in which the demand is escalating enormously and the donation of organs is flat. So the problem gets worse with each passing week.

Back to the direct quote from TRIO. About one-third of the potential donors are never even approached about their options at the time of death of a loved one. Continuing the quote, "organs from one donor can help up to 50 others." So even small increases in donation have huge and beneficial consequences. And there, I think just parenthetically, they must be talking about tissue as organs, it would seem to me.

And by the way, UNOS has testified before your subcommittee in favor of the Shalala allocation rule and the Shalala rule on notification, the entire regulation, again, on the basis of fairness.

All transplant patients understand the concern of fairness. What they do not understand is why a donated organ will go first to a less ill patient in the area where it is generated rather than to a patient from a neighboring area who is at death's door. That they do not understand.

I will conclude now, Mr. Chairman, and I apologize for probably going longer than I should have, but this is a very personal issue to all of us and we think about it a lot. And because of the grace of the Lord and the expertise of my surgeons and the people of this State, I am still around. And I got to finish my Governorship and got a second chance at life. I got to see a lot of my grandchildren I was not supposed to see back in 1993. But I have seen them, thank God. And I want all transplant candidates to have that opportunity to have a new, healthier life because that is what the system should be all about.

So I urge you in the strongest possible terms to, as I hope you will, because I know you are a fighter, this is something worth fighting for. And I appreciate very much the chance to be here today to talk to you.

Senator SPECTER. Thank you very much, Governor Casey. I think it was entirely fitting that at this stage of your career you have another cause, you have another public service issue. You have been in public service for a long time, as a State senator, and auditor general and Governor and I think that it is very appropriate that you have another cause. And your testimony was not at all too long. It is to the point and it is cogent and it is very important.

I think your example as a recipient of organ transplants has done a great deal to notify Americans that organs need to be available to be transplanted. And I think this hearing today will focus a good bit of public attention, again, on the issue of organ transplants and the personal plea, which I echo, that you have made that people should make their organs available. It is of no harm to the individual who is gone and the organs may be used for others.

And I think it is very poignant, as you have commented, that your life was saved, you could finish your term as Governor and you could see more of your grandchildren. When I visited you, Mr. Casey, you commented that you expected No. 27 on Labor Day?

Mr. CASEY. He has arrived.

Senator SPECTER. Wonderful. Wonderful. The Casey family is a national, international model, 8 children, 27 grandchildren. It is wonderful.

Governor, just a question to you on amplification. I said at the outset that I agree with you that the rule promulgated by the Department of Health and Human Services ought to be carried out and it ought to be medical necessity, which all together, we will be fighting to try to get that done. And you may rest assured that I will be quoting you extensively. And I will, in fact, make your testimony available to the other members of the committee, starting with the chairman, Congressman Livingston, who takes a concurrent position.

You have testified that one donor can help many. I would be interested in your amplification of that, if I understood you correctly.

TISSUE

Mr. CASEY. Yes; well, in my case, I do not know this officially, but I believe that my donor saved at least three other people besides me. In other words, I received his heart and liver. But you have the pancreas, you have other organs that can be utilized. And

then, of course, when you add the tissue aspect to it, that expands the——

Senator SPECTER. You say add tissue?

Mr. CASEY. The tissue. In other words, you can donate tissue as well as organs. And I think that is probably where the No. 50 came from. But I know in the case of organs, certainly—for example, I know at the University of Pittsburgh Medical Center they have had transplants procedures where the entire stomach has been replaced, seven, eight organs. But normally they are given to individuals so you can have multiple beneficiaries of just one donation procedure.

Senator SPECTER. You had commented on the circumstances, Mrs. Frances Lucas made available the organs from her son, William Michael Lucas. If you know, what was the time period between the death of Mr. Lucas and the time that the organs were transplanted into your body?

Mr. CASEY. It was very short because of the fact that at that time they had a separate list for heart and liver transplant recipients. My name was the only name on the list. In addition to that, under the criteria, if you are dying, and my doctors told me when I walked in the University of Pittsburgh Medical Center they took some preliminary tests, Doctor Starzl came to my room and said, you could die at any moment. Because I had developed—after I got to the hospital, in addition to the other residual problems that were in my system because of the disease that I had, I developed what is called atrial fibrillation. President Bush had the same thing, if you recall. But it has to do with the electrical system in the heart. And mine was about to——

Senator SPECTER. Who did you say had the same thing?

Mr. CASEY. President Bush had atrial fibrillation. And depending on its severity, it can be fatal. So my doctors told me, just as I told you, you could die at any moment. Now, if that is the case, we talk about medical urgency, that is what we are talking about. So the closer to death the person is, the higher in priority they go. So that combination of medical urgency and that the fact that at that time there was a separate list for heart and liver—it is a very rare procedure. I was the only name on the list and I was at death's door. So those two criteria made it possible for me to get the organs quickly.

Senator SPECTER. You commented that you met Doctor Starzl and up to that time you had been informed there was no cure for your situation. Could you amplify how you happened to meet Doctor Starzl and the conversation which ensued?

Mr. CASEY. Yes; I had a disease called familial amyloidosis, which is a mouthful. But when you have that disease, the liver is not diseased but it produces an abnormal protein. The liver is the protein factory of the human body. If you have familial amyloidosis, the liver produces too much protein and it destroys organs and the strain that I had destroys the heart. Other strains attack other parts of the body.

But Doctor Starzl is who I called. In direct response to your question, I called him because he sent me a copy of his book. This is now May 1993. I had gone 2 years with this disease. And I was told flatly that there was no cure, no treatment and I just had to

live with that. And I was going down physically with each passing day and I knew it.

But I called him not to talk about my condition but just to thank him for sending me a copy of his book. And I said at the end of the conversation just on the spur of the moment, I don't know why I said it to him. Thank God I did because it saved my life. I said, "by the way, what do you know about amyloidosis?" He said, "I will call you back in 5 minutes." I hung the phone up and I sat there for about 5 minutes the phone rang. Governor, Tom Starzl. I can cure you with a liver transplant.

Senator SPECTER. What took him so long to find out?

Mr. CASEY. Well, you have a lot of experience with doctors. It was not on the one hand or the other hand, you know, medical probability, blah, blah, blah. It was, I can cure you. That is the verb he used, cure. And I said, you are my man, let's go. And I went to that hospital and they were going to take a battery of tests and they said, we do not have to see anything else, we know enough, your heart is just barely functioning.

Senator SPECTER. So that was in May and then you got—

Mr. CASEY. Well, now we are in June. May was when I talked to him for the first time and I had, of course, made arrangements to leave the Governorship. And it was an incredible year because, you will recall that Senator Frank Lynch passed away in Philadelphia. And our budget was early that year. We got it May 30. If we had not gotten an early budget, I probably would not be around. It normally goes to July 1, the beginning of the fiscal year. But I made arrangements to go to Pittsburgh quickly. We had a press conference in Harrisburg with Doctor Starzl and Doctor John Fong and saved my life.

Senator SPECTER. Then you went to Pittsburgh to await the availability of the organs?

Mr. CASEY. I went there for testing because they thought I needed a liver transplant. When I went out there, within a day they determined I needed a heart and liver because the heart had been destroyed.

Senator SPECTER. Had there been a previous liver, joint—double liver transplant operation before yours?

Mr. CASEY. There had been four or five, I think, in the country, most of which had been performed at the University of Pittsburgh Medical Center and all of those persons had died.

Senator SPECTER. So yours was the first successful liver—

Mr. CASEY. I believe that to be a fact. There was only one other man in the world at that point, if my memory serves me correctly, in Great Britain who had amyloidosis and a heart/liver transplant.

Senator SPECTER. Now, that ailment was the same ailment which Mayor Caligiuri had or Mayor Tullio of Erie had?

Mr. CASEY. Same name but very different in kind. They had what is called primary amyloidosis, which is a disease of a totally different order. It has a much quicker—

Senator SPECTER. Is there a special susceptibility for elected officials for this ailment?

Mr. CASEY. Is there what?

Senator SPECTER. A special susceptibility of elected officials? [Laughter.]

Mr. CASEY. It might be the water or the air. But Mayor Tullio, whom you knew, and Dick Caligiuri, whom you knew, both had primary amyloidosis. And at that point a liver transplant would not have helped them because their problem was not abnormal protein. It was a different systemic disease. I think it was more of a form of cancer. But they have the same name so when I got sick, people figured that he has got the same thing that the other two people—gentlemen had. But it is very different, essentially different in the sense that by getting a new liver you develop—you get the protein deposition characteristics of the new liver, not of the liver that caused the problem initially.

And Doctor Starzl was smart enough to figure out that this procedure was not medically different in its essence, than procedures that had been going on for a long time in which livers had been transplanted to cure abnormality. For example, one of the best examples of that was the Stormy Jones case whom Doctor Starzl did the surgery. Stormy Jones was a young child from Texas whose liver produced an abnormal cholesterol as opposed to an abnormal protein, which is what amyloidosis does. Stormy Jones had a cholesterol reading that was off the charts. Her organs were clogged with cholesterol. But essentially it was the same medical challenge. Doctor Starzl gave her a new liver and she was cured. I am sorry. He gave her a new heart and liver, identical to mine in terms of the impact of the disease. A completely different disease, but still essentially the same in the sense that by replacing the heart and the liver, the characteristics that produced the illness are eliminated.

Stormy Jones lived for 7 or 8 years and her heart rejected and she died. If she were alive today, she probably would not experience rejection because we now have better immuno-suppression medication and she probably could have been saved.

But Doctor Starzl knew the Stormy Jones case. And my case, that's why he went to the book for a minute. He wanted to see the nature of the strain that I had. Once he determined that, he knew essentially by replacing my liver, just as he replaced Stormy Jones' liver, my condition could be cured if I could live that long. And the question then was, can the heart sustain the insult or the trauma of the liver transplant because when they unhook your liver, they unhook every blood vessel in your body.

And when they put the new liver in and hook it up, it is a very meticulous process of sewing it back together. When they put the blood back in that liver it is such a shock to your system, you must have a strong heart to withstand that initial, what the doctors call insult, to the heart.

Senator SPECTER. So they did the heart transplant first, gave you a new heart?

Mr. CASEY. First.

Senator SPECTER. How long did the operation take?

Mr. CASEY. Well, I think it was 10 or 11 hours, 12 hours, something like that. I know I came out of it sooner than they expected me to, but you know, it is incredible. If someone could explain to me how they can sedate you with drugs and put you under for 13 hours and then bring you back to life. I do not understand that. I mean, that in itself is a miracle to me but they did it.

But, you know, my story is not unique. Bobby Solfanelli and the others you will hear today, everybody has a story. And you know, it is a real life story. And it affects not only the person involved in the procedure but the whole family, before, during and after, it is a family thing.

But when I look back on the improbability of all of these circumstances coming together, an early budget, the fact that I called this man by coincidence really on a totally unrelated matter, and there is more to it which I will not go into other details because I have already gone too long. But I drew the long straw, obviously. And I am very grateful for that.

Senator SPECTER. Well, you are a great example in many ways, Governor Casey. And we will circulate your testimony. I think it will be very influential and we will be fighting to keep the Senate position and to have Secretary Shalala's ruling go into effect.

And it is a question of medical necessity and fairness to the patients and not a matter of dollars and cents or a matter of geography or a matter of parochial interest. It is a matter of doing what is right for the patients. So we thank you very much for coming.

Mr. CASEY. Thank you, Senator Specter.

Senator SPECTER. Thank you, Bob.

[A brief recess was taken.]

STATEMENT OF ROBERT SOLFANELLI, HEART AND LUNG TRANSPLANT RECIPIENT

ACCOMPANIED BY:

JOSEPH SOLFANELLI

NATALIE SOLFANELLI

Senator SPECTER. We will resume our hearing. And we are pleased to have with us Mr. Robert Solfanelli, who is a native of Scranton, graduated from Attica Heights High School. At the age of 3 he was diagnosed with pulmonary hypertension that got progressively worse until he received a double lung transplant in Scranton's Mercy Hospital in 1995.

After his transplant he enrolled at the University of Virginia where he received the Paul Berringer Scholarship for academic achievement and received his bachelor's degree this May. His mother, Natalie, founded a local coalition on organ and tissue donation to promote public awareness and increase the number of those willing to donate. I would very much welcome you here and look forward to your testimony.

Mr. ROBERT SOLFANELLI. Thank you. As you said, my name is Bob Solfanelli. I am now 24 years old and a recipient of a double lung and heart transplant. I am honored to be here this morning to share my thoughts with you. I am sure I cannot speak as eloquently as Governor Casey but I came here to give you my thoughts and my opinions on your proposal.

It is evident to everyone, especially those of us in the transplant community, that the laws governing organ donor allocation are critical and should always be the subject of very careful consideration. The significance of policy regarding organ allocation and patient listing is immeasurable to the 60,000 plus people currently on the transplant waiting lists in the United States.

The most important element of our Nation's organ procurement and transplantation system is that it operates for the greatest benefit of transplant patients. On the whole, I am very happy and impressed with the key principles of the current proposal and it is some of these same goals upon which I would like to place special emphasis today.

STANDARDIZED MEDICAL CRITERIA

This proposal specifically calls for the establishment of standardized medical criteria used to determine the status of a person's illness and when the person can be placed on a waiting list. Although this might, at first, sound like a basic element of this proposal, it is actually a very delicate issue in and of itself. Not only will this criteria be used to determine who is sick enough to be placed on a transplant list, but it also will determine who might be too sick to be listed. Certainly, in many cases, the medical professionals associated with this procedure can determine a patient's chances of post-transplant survival. But there will also be patients who are borderline, those whose chances of survival hover somewhere around 50-50.

It is impossible for doctors to predict the outcome of any transplant, but in these cases it is especially difficult to guess. No one can say which is the greater loss, the patient who might have made a successful transplant recovery but did not meet the criteria to be placed on the list, or the healthy graft that was lost to a gamble on a patient with a weak heart but a strong will to live. As I said, no one can predict the outcome. But we must be very careful when determining the standard by which transplant candidates are judged.

Another major component of this proposal calls for an effort to level the playing field in organ allocation. The idea is to move away from the current regional waiting list into a larger national waiting list. To do this, special status or priority must be given to those patients who are most ill. This is already being done, for example, in the case of heart patients as those who are labeled status 1 are moved to the top of the waiting lists. With other waiting lists, however, like those for patients in need of a lung transplant, there is no way to give priority to the sickest patients.

Allocation is determined solely by time on the waiting list, regardless of medical urgency. Once criteria are in place to categorize the immediacy of a patient's need, I think that the patient of higher medical status should be able to receive a donated organ from another geographic location before a patient with a less urgent need who happens to be closer to the organ donor. For this reason, the move to a national organ waiting list seems to be a great idea.

However, this issue, like the others, has more factors to consider. Most organs are viable for transplantation only for a limited period of time after being harvested. Because of this, the feasibility of a single, nationwide, need-based waiting list becomes questionable. Transportation time and resources must also be considered to avoid wasted organs.

Each of these points to which I have made reference played some part in my own transplant history. I was first evaluated and placed on the waiting list for a double lung transplant in January 1994

at Barnes Hospital in St. Louis. At the time I was told that the average waiting list there was about 7 months and as my name moved to the top of the list I would have to relocate to St. Louis while I waited for my organs.

Well, I decided that I wanted to stay home in Pennsylvania where I could be with my friends and my family. So I moved my name to a waiting list in Philadelphia. Once on that list, those 7 months came and went with no potential donors for me.

My condition continued to get worse during this time and I could actually feel my life slipping away from me. The next thing I knew, a year had gone by since I was first listed for my transplant and I began to wonder if I would even live to see the inside of the operating room.

After 13 months on the waiting list for a double lung transplant, my pulmonary condition had put such a strain on my heart that my doctors determined that I needed a new heart as well as the lungs. Not only did this force me to switch transplant centers, because the one I was at did perform lung transplants but not heart-lung transplants, this also meant that I had to be put on a different waiting list, a list which reflected no accrual of my previous 13 months.

Once listed for the heart, however, I met the criteria for the highest priority and was able to move up the list under those circumstances. By this time, I had grown so sick that I had to move to the hospital as I continued to wait and to hope for the organs that I needed.

Some 4 months after being placed on the list for the heart and lungs, I finally received my transplant. What made my transplant even more unique is the fact that my organs came from a donor in Michigan, an area from which, due to the current allocation system, it is very rare that they have organs in my region. I was extremely fortunate and I cannot express my gratitude for that gift and for that stroke of luck.

My story raises a lot of questions concerning organ allocation procedures. Why did I face a longer waiting time in Pennsylvania than I did in St. Louis? Why is there, at this time, no way on waiting lists for some organs to give priority to those patients with the most immediate need? With such provisions, perhaps I would have received my transplant sooner and would never have needed a heart as well as lungs. That would have been one more organ to save one more dying person.

And when is a patient too sick to be a candidate for a transplant? I am sure that, in the last few months before my transplant, some doctors would have thought that I was too sick to survive the transplant. Yet my condition had only deteriorated that far after nearly 1½ years on the waiting list for lungs which I never received. Fortunately, I had a strong will to live and doctors who believed in my determination who had hope for me. But what if I had not gotten those organs from outside of my region? I probably would not be alive to speak to you today. But mine is just one story, 1 story out of over 60,000 out there right now.

The only real way to eliminate many of the dilemmas associated with organ allocation in this country is to increase the number of organ donors. With enough donors, long waiting lists would be

eliminated, more transplants would be performed and thousands more lives would be saved.

It is my understanding that the proposed rules would allot more money for the promotion of public awareness to the need for organ donors in the United States. As Governor Casey stressed, this new rule would also require that organ procurement organizations are notified of the deaths of potential donors.

For this reason, many more lives could be saved as these potential donor families are approached by trained professionals who can understand their grieving but still help them to determine whether or not they want to make that precious gift.

No one knows the benefits of an organ transplant better than I do. No longer does walking a distance of 30 feet feel like running a marathon. I can now think about my future without wondering if it is too short to consider. In the 3 years since my transplant, I have done many things that once seemed impossible for me. The first thing I did was learn to rollerblade about a month after my transplant. Since then I have seen new places and made new friends. I spent a month last summer studying in London and, most recently, in May I graduated from the University of Virginia. Every day now is a reason for me to smile.

With all of this in mind, I welcome and support the current proposal concerning the allocation of donor organs for transplantation. It is my hope that these rules will address these issues and achieve their goals, thereby making it possible for more people to have a second chance that I have been so lucky to enjoy. Transplants should not be about waiting lists and accidents of geography. They should be about hopes, fears, and dreams. Thank you all for your time.

Senator SPECTER. Thank you very much, Mr. Solfanelli. Your parents are here today?

Mr. ROBERT SOLFANELLI. Yes; they are.

PREPARED STATEMENT

Senator SPECTER. Thank you very much for joining us. Your sister is here as well?

Mr. ROBERT SOLFANELLI. She was not able to make it.

Senator SPECTER. She was not able to make it. Well, She was an intern with our office here and we thank her for her help.

[The statement follows:]

PREPARED STATEMENT OF ROBERT SOLFANELLI

Good morning. My name is Bob Solfanelli, I am 24 years old, and the recipient of a heart and double lung transplant just over 3 years ago. I am honored to be here today to discuss the proposed policies concerning organ donor allocation. The testimony that I submit to you today is based solely on my knowledge of the current proposal, and my own opinions formed from my experiences as a transplant patient.

It is evident to everyone, especially those of us in the transplant community, that the laws governing organ donor allocation are critical and should always be the subject of very careful consideration. The significance of policy regarding organ allocation and patient listing is immeasurable to the 60,000+ people currently on transplant waiting lists in the U.S. The most important element of our Nation's organ procurement and transplantation system is that it operates for the greatest benefit of transplant patients. On the whole, I am very happy and impressed with the key principles of the current proposal, and it is some of these same goals upon which I would like to place special emphasis.

This proposal specifically calls for the establishment of standardized medical criteria used to determine the status of a person's illness and when the person can be placed on a waiting list. Although this might, at first, sound like a basic element of this proposal, it is actually a very delicate issue in and of itself. Not only will this criteria be used to determine who is sick enough to be placed on a transplant waiting list, but could also dictate which patients are too sick to be listed. Certainly, in many cases, the medical professionals associated with this procedure can determine a patient's chances of post-transplant survival. But there will also be patients who are borderline—those whose chances of survival hover somewhere around 50/50. It is impossible for doctors to predict the outcome of any transplant, but in these cases, it is especially difficult to guess. No one can say which is the greater loss—the patient who might have made a successful transplant recovery, but did not meet the criteria to be placed on the list, or the healthy graft that was lost to a gamble on a patient with a weak heart, but a strong will to live. As I said, no one can predict the outcome, but we must be very careful when determining the standard by which transplant candidates are judged.

Another major component of this proposal calls for an effort to “level the playing field” in organ allocation. The idea is to move away from the current regional waiting lists to a larger, national waiting list for those patients with the most serious and immediate need for a transplant. To do this, special status or priority must be given to those patients who are most ill. This is already being done, for example, in the case of heart patients as those who are labeled “status 1” are moved to the top of the waiting lists (although still on a regional level). With other waiting lists however, like those for patients in need of lung transplants, there is no way to give priority to the sickest patients. Allocation is determined by amount of time on the waiting list, regardless of medical urgency. Once criteria is in place to categorize the immediacy of a patient's need, I think that a patient of higher medical status should be able to receive a donated organ from another geographic location before a patient with a less urgent need, who happens to be closer to the donor. For this reason, the move to a national organ waiting list seems to be a great idea. However, this issue, like the others, has more factors to consider. Most organs are only viable for transplantation for a limited period of time after being harvested from the donor. Because of this, the feasibility a single, nationwide, need-based waiting list becomes questionable. Transportation time and resources must also be considered to avoid wasted organs.

Each of these points to which I have made reference played some part in my own transplant history. I was first evaluated and placed on the waiting list for a double lung transplant in January 1994 at Barnes Hospital in St. Louis. I was told that, at the time, the average wait for lungs was approximately seven months, and that I would have to move to St. Louis once I moved near the top of that list. Shortly thereafter, I transferred my name to a list in Pennsylvania so I could remain at home with my family and friends as I waited for a donor to become available. Those first seven months came and went with no potential donors for me. My condition continued to get worse during this time, and I could actually feel my life slipping away from me. The next thing I knew, a year had gone by since I was first listed for my transplant, and I began to wonder if I would even live to see the inside of the operating room.

After thirteen months on the waiting list for a double lung transplant, my pulmonary condition had put such strain on my heart that my doctors determined that I needed a new heart as well as the lungs for which I had been waiting. Not only did this force me to switch transplant centers (the one I was listed at performed lung transplants, but not heart-lungs), but this also meant that I had to be put on a different waiting list, a list which reflected no accrual of my previous thirteen months. Once listed for the heart however, I met the criteria for the highest priority and was able to move up the list under those circumstances. By this time, I had grown so sick that I had to move into the hospital as I continued to wait and to hope for the organs I needed.

Four months after being placed on the list for the heart and lungs, I finally received my transplant. What made my transplant even more unique is the fact that my organs came from a donor in Michigan, an area from which, due to the current allocation system, my region rarely received organs. I was extremely fortunate, and I can not express my gratitude for that gift and for that stroke of luck.

My story raises a lot of questions concerning organ allocation procedures. Why did I face a longer waiting time in Pennsylvania than I did in St. Louis? Why is there, at this time, no way, on the waiting lists for some organs, to give priority to those patients with the most immediate need for transplant? With such provisions, perhaps I would have received my transplant sooner, and would never have needed a heart as well as lungs—that would have been one more organ to give another dying

patient. And when is a patient too sick to be a candidate for a transplant? I'm sure that, in the last few months before my transplant, some doctors would have thought I was too sick to survive. Yet my condition had only deteriorated that far after nearly a year and a half on transplant waiting lists. Fortunately, I had a strong will to live, and doctors who believed in my determination and who had hope for me. But what if I had not gotten those organs from outside of my region? I probably would not be alive to speak to you today. But mine is just one story—one out of more than 60,000 out there right now.

The only real way to eliminate many of the dilemmas associated with organ allocation in this country is to increase the number of organ donors. With enough donors, long waiting lists would be eliminated, more transplants would be performed, and thousands of more lives could be saved. It is my understanding that the proposed rules would allot more money for the promotion of public awareness to the need for organ donors in the U.S. In my opinion, this is the best way to increase the number of lives saved through organ transplants.

No one knows the benefits of an organ transplant better than I do. No longer does walking a distance of thirty feet feel like running a marathon. I can now think about my future without wondering if it is too short to consider. In the three years since my transplant, I have done many things that once seemed impossible for me. I learned how to Rollerblade, I have seen new places and made new friends, I spent a month last summer studying in London, and, most recently, I graduated from college at the University of Virginia. Every day now is a reason to smile.

With all of this in mind, I welcome and support the current proposal concerning the allocation of donor organs for transplantation. It is my hope that these rules will address these issues and achieve their goals, thereby making it possible for more people to have the second chance that I have been so lucky to enjoy. Transplants should not be about waiting lists and accidents of geography—they should be about hopes, fears, and dreams. Thank you very much for your time.

HEART AND LUNG TRANSPLANT

Senator SPECTER. In your testimony you mention your heart as well as lungs. Did you have a heart transplant as well?

Mr. ROBERT SOLFANELLI. I did. I had heart and double lung transplant.

Senator SPECTER. You had a heart and double lung transplant. And that was done all at the same time?

Mr. ROBERT SOLFANELLI. It was all done at the same time in August 1995.

Senator SPECTER. And the donor was from Michigan.

Mr. ROBERT SOLFANELLI. That is correct.

Senator SPECTER. For all the organs?

Mr. ROBERT SOLFANELLI. All the organs.

Senator SPECTER. The heart and the double lungs?

Mr. ROBERT SOLFANELLI. That is correct.

Senator SPECTER. Do you know how long much time elapsed between the death of the donor and the time the organs were transplanted into your body?

Mr. ROBERT SOLFANELLI. I am not sure of the exact time. I know that every resource was used to transport those organs as quickly as possible. But luckily I was in Pittsburgh so I was not as far from Michigan as I would have been if I were still in Philadelphia.

Senator SPECTER. One of the issues which has arisen is the length of time which the organs can last and we had a hearing in Washington earlier this week. And we were told that with respect to the heart that it is a 4- to 6-hour interval.

Mr. ROBERT SOLFANELLI. That is correct. That is once it is harvested from the donor.

Senator SPECTER. I am sorry. I cannot hear you.

Mr. ROBERT SOLFANELLI. As I understand it, that is 4 to 6 hours after that organ is harvested from the donor.

Senator SPECTER. Yes.

Mr. ROBERT SOLFANELLI. So once the organ is harvested, it is important to get out the door and enroute to the waiting recipient.

Senator SPECTER. Do you know if in your case it was by jet, charter jet?

Mr. ROBERT SOLFANELLI. It was either by jet or helicopter.

Senator SPECTER. Jet or helicopter. Well, from Michigan it would probably be by jet. It is a little far to come by helicopter.

Mr. ROBERT SOLFANELLI. Actually, I believe it was a combination.

Senator SPECTER. What was your period of recuperation like? How fast did you recuperate?

Mr. ROBERT SOLFANELLI. I was on my feet and walking around about 4 days after my transplant.

Senator SPECTER. And when did you start the rollerblading?

Mr. ROBERT SOLFANELLI. I got home about a month after my surgery and it was the first thing I wanted to do.

Senator SPECTER. And you graduated with academic achievement this past May?

Mr. ROBERT SOLFANELLI. That is correct.

Senator SPECTER. And how do you feel?

Mr. ROBERT SOLFANELLI. I feel terrific.

Senator SPECTER. When did you first find out that you needed this transplant?

Mr. ROBERT SOLFANELLI. I first found out late in 1993. I had been at Lehigh University. I began my studies there. In Bethlehem the campus is built into a mountainside. And I was there, I began to notice getting around that campus became more and more difficult for me. I finally realized that this was because my condition was getting worse and I went to discuss this problems with my doctor. It was at that time we first decided to look into the possibility of a transplant.

Senator SPECTER. I would be interested to know, and I do not mean to press you on anything that you choose not to answer as to the financing, how expensive was it, how it was paid for. You would have to refer to your father for that?

Mr. ROBERT SOLFANELLI. I would have to refer to my parents for that.

Senator SPECTER. May I ask the parents to come forward, if you would not mind answering that question? What is your first name, Mr. Solfanelli?

Mr. JOSEPH SOLFANELLI. Joseph.

Senator SPECTER. And may the record show that Mr. Solfanelli appears in a Race for the Cure emblem.

Mrs. SOLFANELLI. I will attest to that.

Mr. JOSEPH SOLFANELLI. Natalie is also a breast cancer survivor.

Senator SPECTER. Well, you are very lucky parents and you are a very lucky young man, Robert, to have this complex medical procedure. Mrs. Solfanelli, do you have other children?

Mrs. SOLFANELLI. Yes; we have two other children. We have a son, David, who is a Scranton policeman. And we have a daughter,

Sarah, who is a senior at the College of William and Mary, who worked in your office last summer.

Senator SPECTER. Well, I know she was an intern and I thank her for that. I would be interested to know, and I think my colleagues would, too, if you would be willing to say the cost and the payment for this. Obviously, it is a very expensive proposition.

Mrs. SOLFANELLI. A very expensive proposition. Fortunately, we have excellent medical insurance which covered most of the medical costs. The really very pressing cost, Senator, was all the peripheral things that go along with it, the travel costs. As Bob mentioned, he was first listed at St. Louis at Barnes Hospital where they pioneered lung transplants.

TRAVEL COSTS

The travel cost, the cost of the family to be near him, the housing that would have been required if he had had to move to St. Louis to wait for his transplant there. And, of course, the housing that we had to arrange for while we waited with him in Pittsburgh and various trips to doctors. And it was quite expensive, although, the actual medical costs were pretty much covered by insurance. I have to say, we were fortunate in that regard.

Senator SPECTER. Mr. Solfanelli, what line of work are you in?

Mr. JOSEPH SOLFANELLI. I am an attorney, general counsel for a bank.

Senator SPECTER. Well, thank you very much for your support in the past and for your being here today and good luck to you, Bob.

Mr. ROBERT SOLFANELLI. Thank you very much.

PREPARED STATEMENT OF ELMERETTA B. LECRONE, HEART TRANSPLANT RECIPIENT

Senator SPECTER. We had another—a third witness listed, Ms. Elmeretta Lecrone, a resident of Luzerne County who underwent a heart transplant at Temple University in 1994. She called a little bit before 10 o'clock this morning to say she had been traveling back from Newark, NJ, and her car broke down and had to be towed. So she is unable to be with us today. We have received her statement which we will insert into the record at this point.

[The statement follows:]

PREPARED STATEMENT OF ELMERETTA B. LECRONE

IMPROVING FAIRNESS AND EFFECTIVENESS IN ALLOCATING ORGANS FOR TRANSPLANTATION

My thanks to Senator Specter and this Committee for giving me the opportunity to present these comments. As a heart transplant recipient (Temple University Hospital 1994) and as member of a donor family (1996) I have been personally involved in the organ donation and allocation processes.

One of the most critical factors in organ donation is community awareness. We cannot do enough to expand public knowledge of the realities of organ donation and transplantation. The recent "Share Your Life, Share Your decision" campaign and the National Donor Card Act of 1997 have been very positive initiatives. I believe it is crucial to allocate significant public moneys to support donor awareness through public education programs. The key to saving lives through organ transplantation is in increasing the number of donated organs. More families must come to recognize organ donation as an option when faced with the death of a loved one. It is imperative that people realize this decision is one that is more easily made before tragedy strikes.

The Medicare and Medicaid Conditions of Participation for hospitals, should have a big impact on relieving the donor shortage. They require the referral of all patient deaths to the local Organ Procurement Organization (OPO), and that the OPO or a trained person inform the families of the option to donate and to request consent to do so. The experience in eastern Pennsylvania has suggested that this procedure significantly increases organ donations. I would encourage Congress and HHS to keep these conditions in place in conjunction with increased efforts to continue to expand public education programs.

The Implementation of Federal Rules for the Organ Procurement Transplantation Network, (the Rule) published by HHS in April 1998 raises many questions. I am not a medical professional and I have read a summary of this document, not the document in its entirety. There are some positive ideas expressed, for example the need to standardize the medical and status reporting terminology in the transplant arena. The issue of organ allocation is very complex, and attempts at a solution should involve representation of all the various positions in the transplant community. Decisions such as content of policies that must be adopted concerning organ allocation and patient listing require a formulation process that balances the views of all. I question the capability of a government agency to unilaterally make and/or oversee these decisions alone.

Thinking about "The Rule" really causes more questions than answers to emerge. Some organs, hearts, for example, have an optimum preservation time of 4 to 6 hours. Would a national listing for organs with these shorter preservation times really be practical? Present medical practice allows the organ recipient to be in the operating room prepped and ready for surgery, waiting for the donated organ to arrive. No incision is made until the new organ is in the operating room. Time is crucial. As the preservation time of an organ is lengthened the chances of success of the surgery decline. A regional allocation system is clearly preferable in this type of situation.

"The Rule" indicates that patients should have equal chances to receive an organ based on medical need, not the accident of geography. Waiting times do not always depend on medical need alone. Blood type, body size, the condition of the patient, the availability of the physician—all are contributing factors. Speaking of geography, would a national list really address that problem or would it end up discriminating against those who live in sparsely populated areas? How would placing people on a national list affect the cost and rate of success of transplants? If only the sickest people were transplanted, the rate of success would probably go down. The costs for transplantation would likely go up. The longer one waits, the poorer health becomes. According to "The Rule," I would have probably died before I received a transplant. Though I was able to survive without hospitalization, my heart would have just stopped beating from weakness and deterioration. Because I was not in the hospital, I was not a status 1. On a national list I would have been a nobody. In a regional situation I was able to have the surgery that enabled me to be alive, and to become a productive member of society again. Had I been forced to wait a longer time for my transplant, it is doubtful that I could have resumed such an active life because my condition was deteriorating rapidly and blood was not reaching all bodily areas. Most likely, I would have died with a few weeks.

Perhaps for organs that have a long preservation time it is feasible to have a national list for the sickest patients, but for other organs a regional system would function best due to time restrictions. Other than the very sickest patients, it would seem to me to be very difficult to deal with thousands of people en masse. Even with computers, it would eat up an inordinate amount of valuable time to rank, sort and select candidates, and perhaps some organs would deteriorate past the point of use while we searched through thousands of names. If the name that finally came up was on the other coast it might be too late to send the organ there. Then what?

I would urge this committee to delay the implementation of "The Rule" until allocation policies can be more thoroughly examined. Life is not always fair, as much as we might try to make it so. It is not always possible for us to really know what constitutes fairness. The best way to ensure that more people get lifesaving transplants is to make it a top priority to encourage and support the donation of more organs.

OTHER TRANSPLANT BENEFICIARIES

Senator SPECTER. I am told that there are others in the audience who are beneficiaries of heart transplants. Would you mind standing?

Ms. REILEY. I am a liver transplant.

Senator SPECTER. Would you mind stepping forward and just give us your name for the record? Have a chair. I do not expect the questioning to be more than a half hour for each of you. [Laughter.]

Mr. JOSEPH SOLFANELLI. I may add before these young ladies speak, I do not think about it very often. But when it crosses my mind, it causes me to pause. I am a recipient of two cornea transplants. I had a cornea transplant in my right eye and my left eye, one at Wills and one at Johns Hopkins. If it were not for those transplants I would not have my vision today. I would not be able to see my son recover. So it touches my family in a big way. And I think it affects a number of families throughout this country. It is a family issue and it just changes the whole life of every family.

Senator SPECTER. Thank you very much, Mr. Solfanelli.

STATEMENT OF VALARIE REILEY, HARRISBURG, PA

Senator SPECTER. Would you identify yourself, please, the lady on her right?

Ms. REILEY. My name is Valarie Reiley and I come from Harrisburg, PA. And I had my liver transplant in 1989. And it was done at Pittsburgh, Doctor Starzl's team, and Dr. John Fong was on there, too, with Dr. Louis Milais. And I have a disease called hemochromatosis, which has too much iron in your blood and it is also familial.

And I did not know I had it until it was too late that there is therapy for it. The therapy is to withdraw blood from your system periodically until they get the overload from your system. The overload causes cirrhosis of the liver. And fortunately I had wonderful doctors in Hershey Medical Center who believed in me and wanted me to live and worked very hard with Pittsburgh to get——

Senator SPECTER. And how have you been feeling?

Ms. REILEY. Wonderful. I was always tired all my life.

Senator SPECTER. And you had the transplant in 1989?

Ms. REILEY. 1989. And my twin died 2 years later because it was too late for her.

Senator SPECTER. Your twin died 2 years later?

Ms. REILEY. From the same disease.

Senator SPECTER. Did she need a transplant?

Ms. REILEY. She would have had to have one but she was so sick with a disease, arthritis, osteoporosis from that same disease.

Senator SPECTER. Were you identical twins?

Ms. REILEY. No; we were fraternal twins. But she was not going to the same doctor as I was in Hershey. And I think that physicians make a lot of difference. I was very, very lucky. I have a lot of faith in God and getting to Pittsburgh by jet is how I got through emergency. I only had 5 months to live when I was told that I had this disease and there is nothing they could do about it.

Senator SPECTER. Five months to live?

Ms. REILEY. Yes.

Senator SPECTER. Thank you very much.

STATEMENT OF DIANE ZAPOLSKI, BROOKLYN, PA

Senator SPECTER. Would you identify yourself, ma'am?

Ms. ZAPOLSKI. My name is Diane Zapolski and I had a liver transplant in 1990 at Pittsburgh with Doctor Starzl and Doctor Fong. I had what they called chronic atherotoxic hepatitis caused

by chemicals that I worked with. I have done great since my transplant. They told my family at the time of my surgery——

Senator SPECTER. Where do you live?

Ms. ZAPOLSKI. I live in Brooklyn, PA.

Senator SPECTER. How far is that from here?

Ms. ZAPOLSKI. About 45 minutes.

Senator SPECTER. Well, thank you for coming over today.

STATEMENT OF MARY ANGELI, OLD FORGE, PA

Senator SPECTER. Ma'am, would you identify yourself?

Ms. ANGELI. Yes; I am Mary Angeli. I had my transplant in 1984. I had Berkier's syndrome. And I live here in Old Forge, PA. And I was probably one of the sickest people—I was the sickest person at that time. I was not on a waiting list.

Senator SPECTER. And what did you have a transplant of?

Ms. ANGELI. Liver.

Senator SPECTER. Liver transplant.

Ms. ANGELI. But I was not on a waiting list. And that goes to show you, I went to the top of the list. I was not sick with liver disease. I just got sick in a week or two and I had my transplant.

CONCLUSION OF HEARINGS

Senator SPECTER. Well, thank you very much, ladies, for being willing to share with us that bit of information. We will put that on the record. It will be useful. Thank you very much for coming and that concludes our hearing.

That concludes our hearings, the subcommittee will recess and reconvene subject to the call of the Chair.

[Whereupon, at 11:35 a.m., Saturday, September 12, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]