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DONATED ORGAN ALLOCATION POLICY

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

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DONATED ORGAN ALLOCATION POLICY

FRIDAY, DECEMBER 3, 1999

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

The subcommittee met at 9:30 a.m., in the gold room, Allegheny Courthouse, Pittsburgh, PA, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

Also present: Senator Santorum.

STATEMENT OF DR. WILLIAM F. RAUB, SCIENCE ADVISOR, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. We will begin the hearing of the Appropriations Subcommittee on Labor, Health and Human Services and Education. We will be joined by my distinguished colleague, Senator Rick Santorum, who had other commitments and could not be with us until approximately 10 a.m, but we had already scheduled this hearing to begin at 9:30, and so we will commence on time.

The hearing today will consider the Nation's organ transplant system, which has come into considerable national controversy of events in the course of the past several years. The regulations had been delayed until October 1, 1998, and then were subject to a further delay until October of 1999, and the contentious issues came into focus in the subcommittee which I chair, so that this year we tried to work out the matter to get the regulations implemented in a reasonably prompt manner.

The Senate bill, which came out of our subcommittee, had no delay. Then there were efforts in the House of Representatives to have another year's delay, and that was finally reduced to a delay of 90 days, which in my opinion was too long, and then the matter came to a head in negotiations in a conference which I chaired on November 10.

To get a fuller picture, I asked Secretary of Health and Human Services Donna Shalala to join us and we actually brought her back. She was en route in the early evening of November 10 to Georgetown. She came back to the conference, and for about 1½ hours we had a very spirited discussion, to put it mildly, as to what-all happened.

Secretary Shalala wanted no delay. She was joined in that position by my views, but also by Congressman John Porter, who is the chairman of the House Subcommittee, and urging a longer delay were Congressman Bill Young, who chairs the full House Appropriations Committee and also Congressman David Obey of Wisconsin, who is the ranking democrat on the House Committee, and so we had quite a discussion, and finally we resolved the matter with the 42-day delay, 21 days for comments and 21 days for any changes that the Secretary might want to make on the regulations. I had thought that that was acceptable to the leadership.

We have a curious situation in Washington with subcommittee and full committee chairmen working matters out, but then the package is considered by the leadership, and I had reported all this to Senator Lott and thought we had his acquiescence.

But while that was the final product on the appropriations bill which was signed into law by the President on Monday of this week, October 29, there was an additional provision added to another bill for a 90-day delay, which surprised me, and I wrote to Senator Lott expressing my dismay about that, noting that I did not want to join the growing number of Members who were threatening to hold up the final legislation in Congress. I thought that enough was enough on what we had gone through, that a 42-day delay was adequate.

The law provides that the last bill dominates, and that bill hasn't been signed yet, this worker's bill, but the issue is not concluded, because there will be an effort made to change all that has been done on authorizing legislation next year.

The people who want to upset the regulation are going to have a tough time, because I'm prepared to lead a filibuster in the Senate, and my colleague, Senator Santorum, is prepared to lead a filibuster in the Senate along with me.

Senator Santorum added an important provision in the final appropriations bill, which precludes going through the whole administrative procedure, where there has to be an elongated period for comments and delays, and he worked that out in what is called the colloquy with Senator Lott and Senator Schumer, and I agreed to it, but that was under the leadership of Senator Santorum.

But as I say, this matter is going to come back before the Congress on authorizing legislation next year, but I thought it would be useful to have this hearing today to explore the matter with people in Pittsburgh, because the University of Pittsburgh Medical Center has become a national leader, and I approached this issue as a U.S. Senator on what I think is the best policy for the country as a whole on the Secretary's regulations, and that happens to correspond with what is helpful to the Pittsburgh region on a parochial basis to give recognition to the organ transplant center which we have here in Pittsburgh.

The issue on liver transplants, which is the leading organ issue, shows a great disparity Nation-wide, with Massachusetts having an average waiting time of 569 days for a liver transplant. The Kansas average is 12 days. That puts my State of birth at a considerable advantage over Massachusetts and also a considerable advantage over Pennsylvania, which has the sixth longest waiting period, at 237 days.

The proposed regulations by the Secretary would still give some regional input, but would require the region to be at least populated by some 9 million people, and the statistics show that the number of organ transplants performed each year in the United States has grown from 12,618 in 1988 to almost 21,000 in 1998. The number of centers performing such surgery has grown from 235 in 1988 to 278 at the present time.

The donor availability has grown in a lesser way from slightly under 6,000 in 1988 to more than 9,900 in 1998, but almost 5,000 patients die each year, some 13 a day, while awaiting organ transplantation, and so we're obviously dealing with a matter of life and death, and we want to have a fair system.

PREPARED STATEMENT

We really want to take it out of the province of the Congress to try to get it to the medical experts to see to it that we take care of the sickest first, and have a system which is fair Nation-wide.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ARLEN SPECTER

The Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education will come to order. This morning, the subcommittee will discuss liver allocation policy.

The issue of how to allocate livers to patients has been exceptionally contentious. The Department of Health and Human Services has been proposing new rules to broaden the geographical basis for organ allocation and raising the priority of patients with severe disease. Ever since these changes were proposed, there has been a battle royal between proponents and opponents.

Last year, the Appropriations Committee agreed, with great reluctance, to a 1 year delay in the regulation so that the Institute of Medicine could conduct a study and issue a report. The I.O.M. did so and the Department moved ahead with a revised final rule on October 20. Then came the cry for an additional delay.

During the fiscal year 2000 conference between the House and the Senate on the Labor-HHS-Education appropriations bill, I invited Donna Shalala, the Secretary of HHS, to come to the conference. She was on her way home when we reached her. She immediately turned around and headed back to Capitol Hill. For more than an hour and a half, we had a meeting with the House chairman, Bill Young, who wanted a 90 day delay and the ranking House Democrat, David Obey, who also argued strongly for a delay. I urged that we not have any delay as did Congressman John Porter, chairman of the House subcommittee. Finally we hammered out an agreement for 42 days—21 days for additional comments and 21 more days for a response to those comments.

I had thought that closed the matter and reported back to the leadership. The general rule is to leave these issues with the subcommittee chairmen and we hammered it out. Then I found out that there was another bill with the 90 day extension in it that the President will need to sign.

George Schultz, when he was Secretary of State, once made a prophetic comment that "nothing is ever settled in Washington"—he hit it right on the mark—nothing is ever truly settled inside the beltway. I thought the delay was settled when we struck the deal, but it turned out not to be the case; we may settle it with finality when the delay period expires.

We are here to discuss the HHS proposed rule and what the impact of the delay might mean. We have assembled two panels of witnesses. Our witnesses include Secretary Shalala's Science Advisor, Dr. William Raub; Dr. Reyes (pronounced Rayes) of Children's Hospital of Pittsburgh; Mr. Howard Nathan who runs the Delaware Valley Transplant Group; Dr. Warren Hulnick and Mr. Cleo Gilmore—liver recipients from Pennsylvania.

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

SUMMARY STATEMENT OF DR. WILLIAM F. RAUB

Senator SPECTER. We have two very distinguished panels here today, some witnesses to speak in favor of the Secretary's position, some witnesses to speak in opposition, and we turn now to the panel, and our first witness is Dr. William Raub, the Science Advisor for the U.S. Department of Health and Human Services, previously having served as Science Advisor to the White House Office of Science and Technology, and had been Acting Director of the National Institutes of Health, a native of Alden Station, PA, with a B.A. degree from Wilkes College and a Ph.D in physiology from the University of Pennsylvania, so there is lots of Pennsylvania contacts.

Thank you, Dr. Raub. Our practice in the subcommittee is to put a time limit on for the 5 minutes to allow the maximum time for questions and answers after the testimony is completed, so the floor is yours, Dr. Raub.

Dr. RAUB. Thank you very much, Senator Specter. I appreciate the opportunity to provide comments on behalf of the Department of Health and Human Services (HHS) regarding organ procurement and transplantation in general and the amended rule for the organ procurement and transplantation network, in particular. In developing the original OPTN rule in April 1998 and the amended version in October——

Senator SPECTER. The abbreviation of OPTN?

Dr. RAUB. That is the Organ Procurement and Transplantation Network. HHS has made extraordinary efforts to elicit and consider the views of all parties with an interest in organ procurement and transplantation. HHS remains committed to implementing the rule as soon as authorized to do so.

With your permission, Mr. Chairman, I will submit my full statement for the record and limit my remarks to four points regarding the performance of the OPTN——

Senator SPECTER. Without objection, your entire statement will be made a part of the record.

Dr. RAUB [continuing]. And the role of HHS in fostering reforms. First, organ donation and procurement:

The extraordinary success of organ transplantation over the last several decades has caused demand to exceed supply by a considerable margin. HHS recognizes that increasing organ donation and procurement must be the first priority for everyone involved in organ transplantation.

To that end, in December 1997 HHS launched its national organ and tissue initiative, which has two primary elements: A regulation requiring hospitals participating in medicare to expand their reporting of deaths to organ procurement organizations and a $5 million grant program to learn what works in organ donation.

The regulation is modeled upon Pennsylvania's reporting law and was inspired in part by the success of the Delaware Valley Organ Procurement Organization. We are pleased to report that cadaveric organization increased by almost 6 percent last year, and we are hopeful that the upward trend will continue. Nevertheless, with demand growing faster than supply, we recognize that putting pa-

tients first requires continued emphasis on how organs are shared, which brings me to my second point, equitable organ allocation.

HHS believes that organs should be allocated in a way that treats patients equitably, in accordance with the National Organ Transplant Act, otherwise known as NOTA.

Transplant candidates with essentially equivalent medical emergencies should have essentially equivalent likelihood of receiving an organ, irrespective of their place of residence or the geographic location of the transplant program in which they are registered.

The current OPTN organ transplantation policies fail the test of fairness. That is why implementing the relevant Federal statutes, both NOTA and section 1138 of the Social Security Act, to reduce inequities in organ allocation is one of the principal objectives of the amended OPTN rule.

The Institute of Medicine or IOM shares our concerns about improving the current system of organ allocation. Its congressionally mandated 1999 report entitled, Organ Procurement and Transplantation, includes comments specifically about livers, and I quote:

> The fairness of the organ procurement and transplantation system and its effectiveness in meeting its stated goals would be significantly enhanced if the allocation of scarce donated livers were done over larger populations than is now the case.

Such broad geographic sharing is eminently practical, because, thanks to advances in organ preservation technology, transport of organs over long distances without loss of viability now is routine.

My third point relates to data and information. Deciding whether, when, and where to seek transplantation is a complex, high-stakes task. Patients and referring physicians confronting these decisions deserve up-to-date and easy-to-use information about individual transplant programs. The current OPTN data publication policies fail this test of timeliness and ease of use.

That is why another principal objective of the OPTN regulation is to promote a stream of readily accessible and readily understood reports containing program-specific information that is both accurate and timely. The IOM report also recognizes this need. Recent initiatives by the OPTN contractor in this area are laudable, but further improvements are needed.

My fourth and final point relates to oversight of the OPTN. HHS believes that it must continue to be an active partner with the private sector in pursuing the goals of the OPTN. Indeed, the raison d'etre of the OPTN rule is to clarify the nature and extent of oversight by HHS while strengthening the role of transplantation professionals, patients, patient advocates, and other individuals and organizations throughout the private sector.

The IOM report advocates a strong role for the Federal Government, especially as an advocate for patients, donors, and their families. In recognition of this need, and in response to provisions of the Consolidated Omnibus and Emergency Supplemental Appropriations Act of 1999, HHS has increased its efforts to assess performance of transplant programs.

With the assistance of staff from the United Network for Organ-Sharing, HHS analyzed OPTN patent outcome data for liver and heart transplants. Despite risk adjustments, that is, adjustments for differences in the mix of patients' health from program to program, the analyses revealed substantial differences in outcome

from one transplant program to another. The Department has encouraged the contractor, in its management of the OPTN and its operation of the scientific registry, to broaden the scope of data collection and make increased use of program-specific performance analysis.

PREPARED STATEMENT

In conclusion, Mr. Chairman, HHS believes that the OPTN rule, as amended on October 20, 1999, should go into effect at the earliest possible time. We look forward to further collaboration with you and your colleagues, as well as members of the transplant community, toward our shared goals of increasing organ donation and fashioning a more effective and equitable organ transplantation effort for the United States.

Thank you.

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

[The statement follows:]

PREPARED STATEMENT OF DR. WILLIAM F. RAUB

Good morning, Senator Specter. I am William Raub, Deputy Assistant Secretary for Science Policy at the Department of Health and Human Services (HHS). Thank you for the opportunity to provide comments on behalf of HHS regarding organ procurement and transplantation—including the amended rule that was put forward in October for the Organ Procurement and Transplantation Network (OPTN).

HHS first issued the OPTN final rule on April 2, 1998. This was the culmination of a process that began in 1994 with the issuance of a Notice of Proposed Rule Making, included additional public comment periods in 1996 and 1998, and featured a special three-day public hearing in late 1996 chaired by the then Assistant Secretary for Health, Dr. Philip Lee. In short, HHS made extraordinary efforts to seek out and consider the views of all parties with an interest in organ procurement and transplantation.

Nevertheless, the April 1998 final rule was made subject to a legislatively prescribed moratorium that continued until October, 1999. In association with the moratorium, the Congress called upon the Institute of Medicine (IOM) and the General Accounting Office (GAO) to study key issues related to organ procurement and transplantation and authorized HHS to consult further with the transplant community regarding the rule. In October, 1999, HHS amended the rule to embody the results of its careful consideration of the IOM and GAO reports; its extensive consultations with transplant surgeons, transplant physicians, the United Network for Organ Sharing (UNOS)—the OPTN contractor, patients and patient advocates, and other members of the transplant community; and its analysis of public comments. Recent legislative action would delay the effective date of the amended rule for an additional period. HHS remains committed to implementing the rule as soon as authorized to do so.

The Preamble to the amended rule issued in October includes a detailed description and explanation of the changes HHS made to the original final rule; the pertinent portion of that Preamble is attached for inclusion in the hearing record. The remainder of my statement focuses on several major issues associated with the performance of the OPTN and the role of HHS in fostering reforms to serve patients better.

ENHANCING ORGAN DONATION

The extraordinary success of organ transplantation over the last several decades has caused demand to outstrip supply by a considerable margin. As a consequence, more than 4000 people will die next year while awaiting an organ transplant. Moreover, HHS expects the number of transplant candidates to continue to grow indefinitely.

HHS recognizes that increasing organ donation and procurement must be the first priority for everyone involved with organ transplantation. To that end, in December, 1997, HHS launched its National Organ and Tissue Initiative to foster partnerships between public- and private-sector organizations to enhance public education about

the need for donation and to recruit potential donors. The initiative has two primary elements:

—a regulation, modeled upon legislation in Pennsylvania, requiring hospitals participating in Medicare to expand their reporting of deaths to Organ Procurement Organizations and

—a $5 million grant program to learn more about what works in organ donation.

We are pleased to report that cadaveric organ donation increased by almost 6 percent last year as a result of our collective efforts, and we are hopeful that the upward trend will continue. Nevertheless, with the need for transplantation growing faster than the supply of organs, we recognize that our commitment to putting patients' needs first requires continued emphasis on equitable organ allocation.

EQUITABLE ALLOCATION OF ORGANS

HHS believes that organs should be allocated in a way that treats patients equitably in accordance with the National Organ Transplant Act (NOTA). This means that standardized medical criteria, developed in accordance with sound medical judgment and patient and public involvement, should be the cornerstone of allocation policy. This means that patients should receive organs in a medically appropriate priority order. This means that transplant programs should be monitored to ensure that they are complying with enforceable policies and that education and graduated sanctions should apply to centers that do not comply with the rules. This means that organs should be shared across large population areas, consistent with medical and logistical limits of organ viability, so as to increase the likelihood that medically suitable organs will be available for the highest priority patients. Finally, this means that patients with essentially equivalent medical priority should have essentially equivalent likelihood of receiving a transplant, irrespective of their place of residence or the geographic location of the transplantation program at which they are wait-listed.

The current OPTN organ allocation policies fail these tests of fairness. That is why implementing the relevant federal statutes—the NOTA as well as section 1138 of the Social Security Act—to reduce inequities in organ allocation is another of the principal objectives of the amended OPTN regulation that HHS issued in October.

Our concern about improving the current system of organ allocation system through broader sharing of organs is shared by the Institute of Medicine (IOM) in its Congressionally mandated 1999 report "Organ Procurement and Transplantation". Commenting specifically on allocation of donor livers, IOM concluded that "the fairness of the organ procurement and transplantation system, and its effectiveness in meeting its stated goals, would be significantly enhanced if the allocation of scarce donated livers were done over larger populations than is now the case".

INFORMATION AND DATA

Deciding whether, when, and where to seek transplantation is a complex, high-stakes task. Patients and referring physicians confronting these decisions deserve up-to-date and easy-to-use information about individual transplant programs. The current OPTN data publication policies fail this test of timeliness and ease of use. In particular, program-specific performance data on transplant programs typically are three years old when published and are packaged in a form that the average person has difficulty using. That is why another principal objective of the OPTN regulation is to promote a stream of readily accessible and readily understood reports containing program-specific information that is both accurate and timely—i.e., reports issued at six-month intervals and covering periods ending six-months before the publication date. The IOM report also recognizes this need and calls upon the OPTN contractor to address it. Recent initiatives by the OPTN contractor in this area are laudable, but further improvements are needed.

OVERSIGHT BY THE FEDERAL GOVERNMENT

HHS believes that it must continue to be an active partner with the private-sector in striving to fulfill the goals of the OPTN. Indeed, the raison d'etre of the OPTN rule is to clarify the nature and extent of oversight by HHS while strengthening the role of transplantation professionals, patients, patient-advocates, and other individuals and organizations throughout the private sector. The OPTN rule strives to ensure a predictable and enduring balance among the various groups whose expertise and perspective are indispensable to the OPTN's success.

The IOM report addresses this issue unequivocally:

"The federal government, as well as the transplantation community, has a legitimate and appropriate role to play in ensuring that the organ procurement and transplantation system serves the public interest, especially the needs and concerns

of patients, donors, and families affected by it. The [IOM] learned of numerous instances in which weak governance tends to undermine the effectiveness of the system. . . Weak oversight has compromised accountability at all levels, permitted poor procedures for data collection and analysis to persist, and allowed the system to operate without adequate assessment of performance.

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

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

—the likelihood that, having been listed as a transplant candidate, a patient will receive an organ within one year;

—the likelihood that a patient will die within one year of listing while awaiting transplantation; and

—the likelihood that a patient will still be alive one year after listing, irrespective of whether he or she underwent a transplant procedure.

Despite risk adjustment (i.e., adjustment for differences in the mix of patients' health status from program to program), the analyses revealed substantial differences in outcomes from one transplant program to another.

The principal findings for liver transplants illustrate this:

—ten percent of the programs have a risk-adjusted rate of transplantation within one year of listing of 71 percent or more; whereas, for another ten percent of the programs, the rate is 25 percent or less;

—the likelihood of dying within one year of listing while awaiting a transplant ranges from less than 8 percent to more than 22 percent; and

—the likelihood of surviving one year after listing as a transplant candidate or a recipient ranges from approximately 86 percent to almost 65 percent.

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

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

In conclusion, Mr. Chairman, HHS believes that the OPTN rule, as amended on October 20, 1999, should go into effect at the earliest possible time. We look forward to further collaboration with you and your colleagues—as well as members of the transplant community—toward our shared goals of increasing organ donation and fashioning a more effective and equitable organ transplantation effort for the United States.

NONDEPARTMENTAL WITNESS

STATEMENT OF DR. JORGE REYES, DIRECTOR OF PEDIATRIC TRANSPLANT SURGERY, CHILDREN'S HOSPITAL, PITTSBURGH, AND PROFESSOR OF SURGERY AT THE UNIVERSITY OF PITTSBURGH

Senator SPECTER. We turn now to Dr. Jorge Reyes, Director of Pediatric Transplant Surgery at Children's Hospital in Pittsburgh, and professor of surgery at the University of Pittsburgh. Dr. Reyes has been in Pittsburgh for more than a decade, and in addition to his clinical responsibilities he serves on the Subcommittee for the Development of National Sharing of Split Livers, as well as the

Liver and Intestine Committee of the United Network for Organ Sharing.

Thank you for joining us, Dr. Reyes. Perhaps you could begin by defining for us the term, split livers.

Dr. REYES. Splitting a liver involves taking one category of organ, a donor liver from a brain-dead donor, and separating it into two halves. The smaller half would go to a child, the larger component would go to an adult. It can be done successfully with good graft and patient survival, and it increases the number of patients transplanted.

We can do it after removing the liver or before removing the liver from the cadaveric donor. It gives us the ability to share between centers. We can split a liver here and send a piece elsewhere, or go to another center when we are in dire need of a liver, split it, leave the main larger piece for the recipient locally, and bring the smaller piece for one of our patients.

Senator SPECTER. Is it available only to split it in two? Could you split it in three?

Dr. REYES. At the present time the technology is available only to split it in two.

Senator SPECTER. Thank you very much. Would you start Dr. Reyes' time again, please?

Dr. REYES. Thank you, Senator.

Senator SPECTER. We will not charge you for that. [Laughter.]

Dr. REYES. My message to the committee is simple. The current national allocation policy for liver transplantation is fundamentally unfair, especially for children, and results in a needless loss of life of patients awaiting transplants. Over the last 4 years, alternative allocation policies have been proposed and considered by UNOS that would save more lives and equalize the current large disparities in patient waiting times and deaths.

During the last year, UNOS has grudgingly made small changes to the policies, but those changes have not provided any significant benefit to patients. The regulations proposed by the Secretary of Health have outlined standards for policies that will benefit patients that are waiting for transplantation of all types of organs.

UNOS data and the Institute of Medicine report show that there are wide disparities in the opportunity for patients in similar medical circumstances to receive life-saving organs. The predominant cause of inequities in the system is that donated organs, especially livers, are tracked within the small local service areas of the 63 organ procurement organizations, or OPO's. As a result, patients who are less sick often get priority over others who are more sick elsewhere.

There are those who question the principle reflected in the HHS regulation of providing priority for those who are most medically urgent. This is, however, the current UNOS principle, and the one that UNOS has applied since its inception. UNOS reaffirmed this principle when it adopted regional sharing for Status 1 liver patients this year. It is also a principle supported by the IOM.

One question which UNOS will not answer, however, is why stop with UNOS Status 1 patients? We all agree that those with no chance of——

Senator SPECTER. Why stop with UNOS Status 1 patients?

Dr. REYES. Yes.

Senator SPECTER. Can you amplify that, please?

Dr. REYES. The severity of patients is separated into Status 1, those patients that are in immediate life-threatening situations from hepatitis, from not receiving—for example, they get a bad liver and the liver isn't working. Those patients run the highest risk of mortality.

However, there are those patients with chronic liver disease that are very sick that are in the intensive care unit on life support. Those are Status 2A patients. The chronic liver-diseased patients that are hospitalized but not on life support are 2B, and those patients with chronic liver disease that are home waiting are Status 3.

So for Status 1 the UNOS has supported and has made adjustments to criteria that would support more wider regional sharing for those Status 1 patients. For example, if we have a Status 1 here in Pittsburgh and a liver appears in Philadelphia, and they don't have a Status 1 for that liver, it could potentially come here for our patient regionally. That is supported because it makes sense.

However, we ask, why not make it under a wider sharing region? Why stop at that region, and why stop just for the Status 1, because the Status 1's have shown better survival, but for the Status 2A's the survival is not bad. It's 73.6 percent, and so the survival even for Status 2A's is still good. The argument against 2A's would be that they're not good survivors. Well, we say they are, and the statistics by UNOS supports that, that patients, even if they're chronic liver disease in Status 2A are just as good survivors as the Status 1's.

We all agree that those with no chance of survival should not be transplanted, and the HHS regulation indicates that UNOS should address futile transplants, but the chances of survival of 76.3 percent Nation-wide for the most medically urgent are so good that the system must not condemn these individuals to death based solely on where they live while others who could survive years without a liver transplant receive them.

Patients who come to Pittsburgh for liver transplantation do so for different reasons, including proximity, our expertise with certain types of liver disease, our ability to perform liver small bowel transplants, the lack of medicare approved liver transplant programs where they reside, they are veterans who have a VA program, or they have been turned down at other programs.

We currently have patients waiting from Pennsylvania and from at least 20 other States, yet because of the current allocation policy patients who choose to seek their care here face a chance of receiving an organ that is nearly two times less than the national average.

The performance standard set forth in the regulation can be met without adopting a single national waiting list. Many of these alternatives are superior to the current system, in that there are increased number of lives saved. HHS, which represents no parochial interest, has issued regulations that leave issues of medical judgment with physicians but challenges the OPTN to propose new organ allocation policies that will promote patient benefit and the saving of patient lives at the highest performance criteria.

Critics of the regulation have mischaracterized its contents and have predicted dire consequences. The IOM report specifically addresses those criticisms. Opponents of the HHS regulations have asserted that it will adversely impact the number of donated livers procured each year. This assertion is unfounded, and the IOM found no basis to support this. In fact, UNOS surveys and a Gallup Poll have found the opposite.

I believe in my heart that organ donation is likely to be increased, not decreased, as the general public learns that the system is becoming fair. The sharing of the gift of life across State lines brings us together as Americans by breaking down the geographic boundaries of States and OPO's.

I would also bring to your attention that the major patient group advocates for candidates, recipients, and their families and donor families have all endorsed the Secretary's regulations. These groups know better than others how the public feels concerning organ allocation. Critics of the HHS regulation also claim that it will lead to greater patient travel. I disagree, as does the IOM report. Patient travel is already a part of the transplant system.

The regulation affecting the geography on the donation of organs also has the potential of literally being a life-saver for children awaiting transplantation. A 1998 paper prepared by transplant surgeons from the University of South Carolina suggests a greater geographic sharing of donated organs and more access may save a significant portion of the approximately 75 children who die each year while waiting for a liver transplant.

The data suggest that as many as 600 pediatric donor organs per year are being transplanted into adults, rather than giving those organs the opportunity of being split and saving more pediatric lives.

In conclusion, the Secretary's regulation of the OPTN and organ allocation does not take any medical decisionmaking away from me or from any other transplant surgeon. I will still be responsible for medical decisions.

Moreover, it does not dictate any single national allocation system. Instead, it guides UNOS to develop an alternative policy. It is the responsible role of the HHS to act on behalf of the American public, transplant candidates, and the families of all organ donors, to guide the development of organ allocation policies that are consistent with the spirit of American generosity and compassion.

The IOM report supported the oversight role of HHS as established in the proposed recommendations and recommended more active oversight of and involvement by HHS in organ donation and allocation. Allow the regulation to go into effect and defeat H.R. 2418 and the Senate companion bill, which is a death knell for patients and goes totally against the IOM report.

PREPARED STATEMENT

I want to also express my personal thanks and those of the institutions that I represent to you and to Senator Santorum for the valiant efforts which you have undertaken on behalf of the organ transplant patients of America.

Thank you.

Senator SPECTER. Thank you, Dr. Reyes.

[The statement follows:]

PREPARED STATEMENT OF DR. JORGE REYES

My name is Jorge Reyes, M.D. I am a liver transplant surgeon at the Starzl Transplantation Institute and Chief of Pediatric Transplantation at Children's Hospital of Pittsburgh. My message to the committee is simple: The current national allocation policy for liver transplantation is fundamentally unfair, especially for children, and results in the needless loss of life of patients awaiting transplants. Over the last four years, alternative allocation policies have been proposed and considered by UNOS that would save more lives and equalize the current large disparities in patient waiting times and deaths. During the last year, UNOS has grudgingly made small changes to the policies, but those changes have not provided any significant benefit to patients. The Regulations proposed by the Secretary of Health and Human Services will require UNOS to consider more seriously, and to adopt one of these policies, or others, which benefit the patients awaiting a transplant.

UNOS data and the Institute of Medicine Report show conclusively that wide disparities in the opportunity for patients to receive a life-saving organ exist for patients in similar medical circumstances listed at centers in different parts of the country. If you live in New England and are listed at a transplant center in Boston, the IOM report clearly shows that your chances of receiving an organ in time to save your life are substantially lower than if you are listed at a transplant center in Nashville, Tennessee. These differences are unfair and unnecessary.

The predominant cause of inequities in the system is that donated organs, especially livers, are trapped within the small, local service areas of the 63 organ procurement organizations, or OPOs, that are currently active. With one exception, donated livers are offered to all patients within an OPO service area before being offered to any patients outside of that area. As a result, individuals who are less sick often get priority over others who are more sick elsewhere. The exception, as the result of a recent UNOS change, is that in most instances, a liver will be shared within one of 11 UNOS Regions for a Status 1 patient, before being offered to Status 2A, 2B or 3 patients in the OPO area.

The operation of the current policy in a more usual circumstance is best shown by an example. Consider a transplant center with a waiting list where one patient has a short 7-day life expectancy, and a second patient not yet hospitalized for his liver disease. The more medically urgent patient meets the definition of UNOS Status 2A, and the other is in UNOS Status 3. Say that both patients are the same weight, age and blood type. If a compatible organ is procured in the OPO servicing the transplant center, UNOS' current liver allocation policy dictates that the donated liver would go to the Status 2A patient, if there is no compatible Status 1 patient in the region. This makes sense, since the Status 2A patient will die soon without a transplant. Consider, though, if these two patients are listed at centers in separate geographic areas. If a donated liver becomes available within the OPO of the Status 3 patient, that patient would receive the organ, if there is no compatible Status 1 patient in the region, while the Status 2A patient would continue to wait, and potentially die while waiting.

At some transplant centers the vast majority of transplants performed are on Status 3 patients, while at the same time more medically urgent patients wait and die elsewhere in the country. Although Status 1, and the less urgent Status 2A patients, comprise only a tiny fraction (approximately 2 percent) of the candidates waiting for liver transplants in the U.S. at any time, they account for nearly half of the patient deaths on the waiting list.

Consider this example from 1998. We had a young child in our hospital as a Status 1 patient. He was critically ill, in need of a liver and small bowel, and was listed at the University of Miami as well. Organs became available in Miami's UNOS region and arrangements were being made to send the organs to Pittsburgh until a surgeon from another Florida program insisted that the organs remain local for transplant into a Status 3 child. The next day the patient in Pittsburgh died. Had we received the organs from outside our region this child might be alive today.

There are those who question the principle reflected in the HHS regulation of providing priority for those who are most medically urgent. This is, however, the current UNOS principle, and the one that UNOS has applied since its inception. UNOS reaffirmed this principle when it adopted regional sharing for Status 1 liver patients this year. It is also a principle supported by the IOM. One question which UNOS will not answer, however, is why stop with UNOS Status 1 patients? We all agree that those with no chance of survival should not be transplanted and the HHS regulation indicates that UNOS should address futile transplants. But the chances of survival (76.3 percent nationwide) for the most medically urgent are so good that

the system must not condemn these individuals to death, based solely on where they live, while others who could survive years without a liver transplant receive one.

The patients on the waiting list in Pittsburgh are disadvantaged by the inequities in the current system, as are patients at numerous other transplant programs, large and small, across the country. Patients who come to Pittsburgh for liver transplantation do so for different reasons, including: the proximity of their residence, our expertise with specific types of liver disease, our ability to perform liver small bowel transplantation (one of only three programs in the country that routinely perform this procedure), the lack of a Medicare approved liver transplant program in their area, they are a veteran of the U.S. Military or, because they have been turned down by other liver transplantation programs. We currently have patients waiting from Pennsylvania and from at least 20 other states. Yet, because of the current allocation policy, patients who choose to seek their care here face a chance of receiving an organ that is nearly two times less than the national average.

The performance standards set forth in the regulation can be met without adopting a single national waiting list. Many of these alternatives are superior to the current system in that there are an increased number of lives saved. Over the past several years, a wide variety of alternative policies have been considered by UNOS committees, but only one regional sharing plan, for UNOS Status 1 liver patients, has been adopted. Many of the proposals are superior to the current system and meet the provisions of the regulation. The IOM Report recommended a policy of organ distribution in areas of not less than 12 million people as a way of benefiting patients and having a more equitable system. At a May 7, 1998 meeting of the UNOS Liver and Intestine Committee, a motion was passed that the Committee could indeed develop a policy that meets the policy goals of the regulation, while avoiding some of the logistical difficulties attendant to a single national list policy. Recent statements by UNOS at its November 1999 Board meeting reaffirmed that UNOS can adopt policies that comply with the regulations. Given these admissions that UNOS can comply with the Regulations, UNOS should propose such allocation policies now.

HHS, which represents no parochial interest, has issued regulations that leave issues of medical judgment with transplant doctors, but challenges the OPTN to propose new organ allocation policies that will promote patient benefit and the saving of patient lives as the highest performance criteria.

Critics of the regulation have mischaracterized its contents, and based upon the mischaracterization have predicted dire consequences. The IOM Report specifically addressed the criticisms and concluded that they were essentially without merit. I would only add a few comments about criticisms of the regulation for the committee's consideration:

PROJECTED ADVERSE IMPACT ON DONATION

Opponents of the HHS regulations have asserted that it will adversely impact the number of donated livers procured each year. This assertion is unfounded and the IOM found no basis of support. In fact, when UNOS surveyed the general public in 1994, it learned that 60 percent of recipients, and 58 percent of candidates, assigned the lowest priority to keeping organs locally. 54 percent of recipients and 50 percent of candidates assigned top priority to the patient who has the least amount of time to live. Making waiting time "about the same for all patients nationally" was a top priority for over one-third of those surveyed. Similarly, in an OPTN poll in 1990, over 75 percent of respondents disagreed with the statement that "donor organs should go to someone in the area where the donor lived." The attitude of donor families is well illustrated by the testimony of Patricia Hodgson to the Human Resources Subcommittee of the House Government Reform and Oversight Committee at a hearing on April 8, 1998, in Milwaukee, Wisconsin. Ms. Hodgson is a nurse who donated her husband's organs. Her testimony included the statement:

"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."

We know that the people of Pennsylvania are encouraged by the recovery of Daniel Canal, a 13-year old Maryland boy who received a multiple organ transplant in Miami with organs donated by a generous family in Pennsylvania. I believe in my heart that organ donation is likely to be increased, not decreased, as the general public learns of more events such as this. The sharing of the gift of life across state lines brings us together as Americans by breaking down the geographic boundaries of states, and OPOs.

I would also bring to your attention that the major patient groups—advocates for candidates, recipients and their families, and donor families—such as the American Liver Foundation, Transplant Recipients International Organization, National

Transplant Action Committee, and the Minority Organ and Tissue Transplant Education Program, have all endorsed the Secretary's regulation. These groups know better than others how the public feels concerning organ allocation.

PATIENT TRAVEL

Critics of the HHS regulation claim that it will lead to greater patient travel. I disagree as does the IOM Report. Patient travel is already a part of the transplant system. Indeed, equalizing the chances for patients to receive a donated organ will remove one of the several incentives for patients to travel to a distant center.

Based on findings of the IOM, one out of four transplant recipients traveled out of state to receive a liver transplant. For 46 percent of the population, including the residents of the 14 states without a liver transplant center, travel is a necessity. Many other liver candidates choose to travel out of state, even if there is an in state program, for such reasons as: to seek the expertise of a specific center with regard to their condition, to comply with the dictates of health care insurance, to avoid a high mortality rate or long waiting times at a local center, or due to the refusal of a local center to list the patient. And although these patients traveled out of state, organs procured in their state of residence generally did not follow them.

Finally, when you consider that 32 percent of Louisiana patients and 28 percent of Oklahoma patients, according to 1994 and 1995 UNOS data, travel elsewhere for their transplants you have to wonder if their recently enacted state organ hoarding laws truly benefit all the residents of those states.

Critics also contend that Medicaid beneficiaries will be hurt by these regulations because of patient travel concerns. Again, the IOM Report found there was no basis for this criticism.

PROTECTION OF PEDIATRIC PATIENTS

The regulation, by curtailing the effect of geography on the allocation of donated organs, also has the potential of literally being a "life saver" for children awaiting transplantation. A 1998 paper prepared by transplant surgeons from the University of South Carolina and UNOS suggests that greater geographic sharing of donated livers and more access may save a significant portion of the approximately 75 children who die each year while waiting for a liver transplant. There are a limited number of pediatric transplant centers and many OPO service areas and some UNOS regions have none. The data from the study suggest that as many as 600 pediatric donor organs per year are being transplanted into adults, rather than children, in part because the organs are donated in areas with no pediatric transplant centers or patients. Since many pediatric patients are in Status 1 or 2B, they will benefit from the performance standards in the regulation which call for more equal access to organs for the sicker patients in wider geographic areas.

CONCLUSION

The Secretary's regulation of the OPTN and organ allocation does not take any medical decision-making away from me or from any other transplant surgeon. I will still be responsible for medical decisions regarding my patients. Moreover, it does not dictate any single liver allocation system. Instead, it guides UNOS to develop an alternative policy, perhaps similar to one of the many that UNOS has considered over the past several years, and to propose it to the federal government for review.

It is the responsible role of HHS to act on behalf of the American public, transplant candidates and the families of all organ donors, to guide the development of organ allocation policies that are consistent with the spirit of American generosity and compassion. The IOM Report supported the oversight role of HHS as established in the proposed regulations and recommended more active oversight of, and involvement by, HHS in organ donation and allocation. The voice of the public has been heard and it says to share the gift of life with the most medically urgent transplant candidates no matter where they live. The voice of the IOM, in a study specifically commissioned by the U.S. House and Senate, has also been heard supporting the regulations and the policies which they establish. I urge this Committee to hear these voices. Allow the regulations to go into effect and defeat H.R. 2418, and the Senate companion bill, which is a death-knell for patients and goes totally against the IOM Report.

I want to also express my personal thanks, and those of the institutions that I represent, to you and to Senator Santorum for the valiant efforts which you have undertaken on behalf of the transplant patients of America. We know you care and that helps.

NATIONAL SYSTEM OF FAIRNESS

Senator SPECTER. Senator Santorum has joined us. I will yield to him in a moment before we turn to Mr. Nathan, but before we do, I want to summarize briefly what we have talked about.

At the outset I summarized the background as to the negotiations with Secretary Shalala and the conference on the subcommittee bill, and how we had sustained a year's moratorium last year, and they had wanted another year's moratorium and reduced it to 90 days.

We had negotiated a 42-day period, and then a subsequent bill added back the 90-day period, and I told them about your leadership in the colloquy with Senator Lott and Senator Schumer, specifying that there would not be within any period the necessity to go back and have comments and republication on the extension of procedural steps.

I also said that the purpose of this hearing was to get more factual information because the matters will be before the Congress again next year with the candid statements of those who oppose the regulation trying to nullify it, and our commitment, yours and mine, to lead a filibuster which would require 60 votes to cut off, and if that were to be achieved, which I think unlikely, that a presidential veto would be in order to back up Secretary Shalala's position, and that would require 67 votes.

But we wanted to have this hearing to get the specifics on a national system of fairness, which coincidentally is of benefit to the University of Pittsburgh Medical Center and much of this region.

So with that brief summary, I will yield to you, Senator Santorum.

OPENING STATEMENT OF SENATOR RICK SANTORUM

Senator SANTORUM. First of all, let me congratulate you for holding this hearing and more importantly congratulate you for the excellent work you have done on behalf of this issue. As chairman of the subcommittee you have been besieged, now, for 2 years, and I know this was one of the last remaining issues that you had to deal with in trying to get your bill done, and to stand up, as you did, to our Leader in the Senate and to last year the Speaker of the House, or who was to be the next Speaker of the House, the chairman of the Appropriations Committee, Bob Livingston, and a whole host of other people who have been fighting this battle on the other side.

You have valiantly stood in the trenches and were able to achieve the 42-day, subsequently 90-day moratorium which effectively—and I think that is the point that I tried to make to my colleagues, which effectively is 180 days, because it is 90 days before the Secretary's role becomes effective, then UNOS has 90 days to develop a liver transplant policy and a year, better than a year to develop a transplant organ allocation policy for all other organs.

So for those who are concerned that the Congress will not have time to make a statement, to act on this issue, there is plenty of time if there is a serious desire on anybody's part to deal with this issue congressionally.

The system we are operating under was due for reauthorization back in 1993, and so when a lot of people came forward to me and to Senator Specter and said, look, we need this delay because we are going to bring up the reauthorization, we need to have time to reauthorize this bill, I said, you have had 6 years to reauthorize this bill and to say that somehow or another you are going to wave your wand and get it done next year because we are going to give you another moratorium—that is what Congressman Livingston told me last year when I got into a shouting match with him on this issue, that he needed another year to reauthorize the bill.

This is a very controversial subject. It is a very controversial subject because you have—and I hate to put it in these terms. You have, I believe, one side of the issue that is driven by economics, and economic survival, and it is a very different world in the smaller transplant centers, or the newer transplant centers, than it is in the older and established centers, and they are in need of organs to basically survive in business.

When you see the States reacting like Louisiana and New Jersey—and I think there are four or five others who have said that no organs can leave their States. I looked at Louisiana, for example, that I think 68 percent of the people in Louisiana that get transplants get them from outside of Louisiana, so here are people from—their own citizens who cannot get organs from people in their States, because they keep the organs. Now, does that benefit the citizens of Louisiana, or does it benefit the transplant centers in Louisiana?

So who are we really trying to benefit here, the citizens or the economy, and that is the reason I have gotten so passionate about this issue, because this should not be about economics. This should be about saving people's lives, and the system that the Secretary—and Dr. Raub knows this. I do not often agree with the Secretary, but on this issue I could not agree more with the Secretary, and I have stood shoulder to shoulder with her in trying to make sure that this allocation system can move forward so we can begin to save lives that are needlessly being lost in this country, not just here in Pittsburgh but all over the country.

We are going to continue to fight this battle. This is not even close to being over. We are really in the thick of it. There will be a reauthorization. Senator Frist has promised that he will try to move a reauthorization out of the Labor Committee in the early part of next year. I have talked to Senator Frist. I think he comes at this issue from an honest perspective, and I am hopeful that he will try to move a fair bill.

But as Senator Specter said, this is not a bill that reflects in the best interest of patient care and is in the best interests of the people who are on those lists who desperately need these organs to survive, and Senator Specter and I will block this legislation to the last drop of our blood on the floor of the Senate.

Senator SPECTER. We may need transplants. [Laughter.]

Senator SANTORUM. We may need transfusions. I do not know about transplants. But to me this is that important an issue. It is not about economics. There are transplant centers in and around Pennsylvania that are not supporting this proposal. There are those here that do.

This is about doing what is right for patients, and I want to associate myself with my good colleague and senior colleague from Pennsylvania for his excellent work, and look forward to working with him to make sure that these regulations or something very similar to it are finally enacted into law and we have a fair organ allocation policy.

Senator SPECTER. Thank you very much, Senator Santorum. I would say that you and I stand shoulder-to-shoulder with Secretary Shalala. That is three blocks of granite.

STATEMENT OF HOWARD M. NATHAN, PRESIDENT AND CEO, GIFT OF LIFE DONOR PROGRAM, PHILADELPHIA, PA

Senator SPECTER. We now turn to our third distinguished panelist, Mr. Howard Nathan, who is president and CEO of the Gift of Life Donor Program in Philadelphia, which is the organ procurement organization for the entire Delaware Valley. He has been with the Delaware Valley Transplant Program for more than two decades and is responsible for the coordination of organ procurement and allocation in Eastern Pennsylvania.

A native of Johnstown, he earned his bachelor's degree from Juniata College in Huntingdon and attended both the University of Pennsylvania and the University of Pittsburgh, so your credentials are excellent. Just do not run for State-wide office. [Laughter.]

Mr. Nathan and I chatted briefly. He has an opposing view to Secretary Shalala's regulation, and it is our practice and the practice generally in the Congress to hear all points of view, regardless of what the Senators on the subcommittee might think.

Welcome, Mr. Nathan, and the floor is yours.

Mr. NATHAN. Thank you, Senator Specter and Senator Santorum. I appreciate the opportunity.

As the Senator said, I am from the Philadelphia area, but we cover the eastern half of Pennsylvania for organ donation, which represents actually about two-thirds of the State's population. My organization, Gift of Life, has been around for 25 years. It used to be called Delaware Valley Transplant Program until this year. It represents 12 hospitals that perform organ transplants and 3,000 patients awaiting organ transplantation.

We are proud of our efforts here in Pennsylvania. Our sister organization, CORE, which is based here in Pittsburgh, has some of the highest donation rates in the country because of comprehensive State laws that have been implemented to increase donations.

Just to give you an idea, in the last 2 years, in 1997 and 1998, our organization was the number 1 program in the country, with 291 organ donors in 1997 and 298 in 1998, representing over 1,850 life-saving transplants. This year to date our organ donors have gone over 300 for the first 11 months, representing 930 patients who received transplants. We are very proud of that record, and we are hoping that some of the things that we have done that I will talk about later federally will emulate Pennsylvania's success.

One of the things that I guess I regret to report is that I feel that the current media debate about allocation has cast doubt in the public's mind about the system that really has aided hundreds of thousands of people who have received organ and tissue transplants over the past several decades.

My feeling is by continuously focusing on allocation instead of the real issue of increasing donations the public attitude toward donation may have been negatively impacted. Gift of Life does not disagree that organ allocation policies must be continuously evaluated, appropriately updated, and administered in an equitable and fair manner, but we strongly urge that careful consideration be done so that the manner in which it occurs is different than it is today, in the front headlines of the papers.

To date, I feel that there has been a lack of focus, and that changes of the allocation system of the OPTN that have been implemented have actually changed some of the things that we have been arguing about over the past 3 years. One of which we talked about was this Status 1 sharing of livers regionally so that patients within a certain region of the country who are the sickest get priority for an organ that becomes available.

One of the things we are concerned about with the regs is, we believe it gives the Secretary unilateral authority that is contrary to the intent of NOTA and in some cases to the Secretary's own comments. We believe that the current system allows for open debate with Government input, among the medical community and the public, for continuous evaluation and policy change regarding broader organ-sharing.

As you said before, the Gift of Life certainly agrees with the IOM report that the provision of the final rule for organ-sharing take place over as broad a geographic area to ensure that organs reach the appropriate patients is appropriate. In fact, the OPTN contractor has implemented that, as I said, with this Region 1, or the regional status-sharing.

Interestingly, the size of the population base is about 9.8 million, which is similar to our population in the Gift of Life area, and we recognize there may be a need to expand the sharing areas in other parts of the United States, as Senator Santorum said, in smaller parts of the country where the population bases aren't that big and that patients who are not as sick get transplants.

I see my time is running short.

Senator SPECTER. You can take a little longer, Mr. Nathan.

Mr. NATHAN. Thanks. We feel that, moreover, establishing broader organ-sharing policies through the population base and waiting time rather than other issues, including things such as geography, may be unfeasible in certain parts of the country, because organs have a limited viability outside the body.

There are numerous situations where transplanting an organ quickly is required. All donor organs are not created equal, and what I mean by that is, as the transplant surgeons are continuously trying to expand the donor pool, such as utilizing organs from older-aged donors—as old as 82 years old livers have been successfully transplanted—the only way that surgeons will use those organs is if they can transplant them within hours of the removal, and in some cases that sharing is not possible, and those are the type of things that I think medical judgment has to come into play to make decisions about when we are setting up organ allocation policies.

Issues surrounding data collection, as Dr. Raub indicated, the Secretary would like more information available to patients making

decisions about transplantation. We agree with that, but we also feel that the current OPTN contractor has some of the best medical information for patients in the country, and it is now online through a system called UNET, which provides a great deal of information on listing outcomes for specific transplants, and is accessible to all members of the community.

Our issue focuses along this area regarding the Secretary's ability to hold unilateral decisionmaking. We also feel that the development of the Advisory Council is somewhat redundant, because it really exists through much of the medical community that already participates in the extensive debates through the OPTN contract.

One other issue has to do with OPO performance criteria. One of the issues right now is that some OPO's may be decertified by the Health Care Finance Administration, because of what is called poor performance. I do not disagree that every OPO should do whatever they can, and I feel that they do try to perform as well as possible, and in certain instances there may be a need for replacement of organizations. However, until performance criteria are well-defined, I do not think that any organization should be decertified.

Some of the amendments reflected, as well as the amendment in the NOTA bill, say that HCFA should work with the organ procurement organization to issue organ procurement certification standards that make sense.

Last but not least, as I indicated, we are very proud of the success here in Pennsylvania. In our region of the State, two-thirds of the State, organ donation has increased 65 percent just in the last 2 years, and the number of transplants available has increased 70 percent. Our sister organization, CORE, this year has begun to experience increased organ donation rates, and has always been a high performer.

We are hopeful that the Federal rules implemented for routine referral will continue to increase procurement, and my feeling is that the system is not totally broken. What we must do, as citizens of the country, is to make sure that more and more focus becomes on organ donation rather than organ allocation.

Thank you very much.

Senator SPECTER. I thank you, Mr. Nathan.

[The statement follows:]

PREPARED STATEMENT OF HOWARD M. NATHAN

I am Howard M. Nathan, the President and C.E.O. of Gift of Life Donor Program ("Gift of Life"). Gift of Life is the nonprofit organ procurement organization ("OPO") that serves patients and hospitals in the eastern half of Pennsylvania, Southern New Jersey, and Delaware and has a population base of 9.8 million. For over 25 years, Gift of Life has served more than 160 acute care hospitals in the tri-state region; it has been certified by the Health Care Financing Administration ("HCFA") since 1988 as the OPO for its service area.

Gift of Life currently serves over 3,300 patients awaiting life-saving organ transplants at 12 regional transplant hospitals. In addition, it has cooperative relationships with three regional eye banks and three tissue banks. Gift of Life has consistently been recognized as one the nation's top performing OPOs. We are proud of our efforts on behalf of the patients we serve. In 1997 and 1998, Gift of Life was the most active OPO in the United States, coordinating a national record number of organ donors (291 and 298 respectively) for any OPO service area in the United States resulting in 1,844 life saving transplants. Gift of Life's performance year to date in 1999 again places it as the most active OPO in the country. We have again

coordinated a national record number of 308 organ donors the first 11 months of this year coordinating over 930 transplants year to date.

I am also appearing today as President of the national Coalition on Donation ("Coalition"). The Coalition is an alliance of the entire transplant community, including 48 national organizations and 50 local grassroots coalitions with the primary mission of educating the public about organ and tissue donations and creating a willingness to donate. You may be familiar with the Coalition's unified national message, "Share Your Life, Share Your Decision" which was developed by the Ad Council and utilized in the Coalition's highly visible Michael Jordan public education campaign, as well as the Ad Council campaigns on organ and tissue donation. Numerous partnerships with nationally recognized advertising and media agencies have been formed to utilize these talents and deliver a common message to the public. Other partnering efforts have been undertaken. For example, supported by Congress' efforts in enacting the National Donor Card Insert Act, the Coalition worked with the U.S. Department of Treasury and Department of Health & Human Services in 1997 to provide 70 million people the opportunity to indicate their wish to become organ or tissue donors by including donor cards in the envelopes that contained IRS tax refunds. I believe it is critical that we refocus the nation's attention on donation if we are to combat the donor organ shortage.

My other experiences in transplantation include past President of the Association of Organ Procurement Organizations ("AOPO") and three times elected to the Board of the current Organ Procurement and Transplantation Network ("OPTN") contractor, the United Network for Organ Sharing.

Working with Gift of Life and our elected representatives, as well as other organizations such as the Coalition on Donation, AOPO, and UNOS for more than 20 years, has granted me the opportunity to work closely not only with transplant hospitals and OPOs, but with donor families and transplant recipients at both the local and national levels. I understand that a single message regarding donation must be communicated through comprehensive public education initiatives. This, in conjunction with providing all potential donor families with the donor option, is critical to combating the organ donor shortage.

Regrettably, I must report that the current debate in the media regarding organ allocation has cast doubt on a system that has aided hundreds of thousands of patients. By continuously focusing on allocation instead of the real issue—increasing organ donations, the public's attitude towards organ donation may have been negatively impacted. Gift of Life does not disagree that organ allocation policies must be continuously evaluated, appropriately updated and administered in an equitable and efficient manner, but strongly urges that careful consideration be given to the manner in which those acts occur. To date, Gift of Life believes there has been a disturbing lack of focus on the changes in the organ allocation and listing policies that have already been implemented by the OPTN contractor in cooperation with the transplantation community during the past three years. At the same time the important issue of increasing organ donation has taken a "back seat" rather than being the primary focus.

Today, I will highlight those aspects of the October 20, 1999 Rules regarding the Organ Procurement and Transplantation Network (the "Final Rules") that I support, as well as those areas in which I believe the Final Rules will not further the interests of patients nationally. I will also provide data on the success of measures that have been undertaken to increase organ donation in this country and offer a challenge to the Congress to further commit its resources to organ donation efforts.

THE FINAL RULES CONTINUE TO PROVIDE THE SECRETARY WITH UNILATERAL AUTHORITY CONTRARY TO THE INTENT OF NOTA AND THE SECRETARY'S OWN COMMENTS

Gift of Life recognizes the efforts of all within the public and private sectors of the transplant community to fully evaluate and consider the issues surrounding allocation and to identify policies that will fairly deal with patients. Gift of Life supports certain of the policy positions highlighted in the Preamble to the Final Rules and the Final Rules itself. However, Gift of Life maintains the position that ultimately many of these issues are medical issues, and that the Final Rules continue to allow for excessive discretionary decision making by the Secretary on medical issues. We believe that the current system (OPTN) allows for open debate among the medical community and the public for continuous evaluation and policy change.

Policies for the equitable allocation of organs

Broader regional sharing

Gift of Life agrees with the Institute of Medicine ("IOM") Report and the provision of the Final Rule providing that organ sharing take place "over as broad a geo-

graphic area as feasible" to ensure that organs can reach the patients who need them most, and for whom transplantation is appropriate. In fact, the current OPTN contractor has already implemented broader sharing policies, such as regional sharing of livers for Status–1 patients. Gift of Life serves a population base of approximately 9.8 million, similar to the optimal size recommended by the IOM and critically ill patients can routinely receive organs if regional organ donor efforts are effective. We also recognize that there may be a need to expand the sharing in other parts of the United States where population bases are somewhat smaller. As noted above, Gift of Life's organ and transplantation efforts have experienced significant growth in the last several years. Gift of Life attributes this growth to the successful partnering with the hospital and community on "Routine Referral" laws and the suitability criteria applied by its regional transplant centers and surgeons. In particular, Pennsylvania Act 102, passed in 1994, has been a national model for increasing organ donations.

However, neither the Final Rules, nor accompanying statements, recognize or contemplate the concerns voiced by the medical community that broader regional sharing to provide for the transplant of the sickest patients first might result in adverse patient outcome and survival rates. This is an issue that must be the subject of ongoing evaluation and monitoring. The process of developing and modifying the allocation policies must be sufficiently flexible and dynamic to allow for ongoing change. Our concern is that the Final Rules do not allow for this type of dynamic process given the timeframes provided for and the role of the Secretary.

Moreover, establishing and applying "broader organ sharing policies" solely through population base, rather than other issues (including other limitations, such as geographic ones) may be infeasible in certain parts of the country. Because organs have a limited time of viability outside of the body, there are numerous situations where transplanting an organ quickly is required. All donor organs are not created equal. Transplant surgeons are continuously trying to expand the donor pool such as utilizing organs from older age donors, and the viability and ultimate utilization of such an organ may be compromised through broad based sharing. Therefore, medical judgement must always be considered. Shorter cold ischemic times (time donor organ is outside of the body) result in more successful transplantations and significantly less wastage.

Patient listing criteria

Gift of Life also acknowledges and supports the changes that have already been made by the OPTN contractor to the patient listing criteria applicable to liver and heart patients. While historically there have been discrepancies in waiting times by region, those discrepancies were in a large part based on a system of listing patients that is no longer prevalent with the above policy changes. We also believe that it will be impossible to equilibrate waiting times as a primary measure in organ allocation since medical factors should always take precedent.

Data collection protocols

We concur with the emphasis on the collection of data as provided in the Final Rules. We note, however, that one of the best medical databases in the country is the one that has been established by the OPTN contractor. The UNET system provides for comprehensive data on listing, outcomes and specific transplant centers and is accessible to all members of the public. In order to evaluate the success of any organ allocation and other transplantation policies, including those most recently implemented by the OPTN contractor, all of the participants must commit resources to the timely development and accessibility of data.

Medical decision making

Gift of Life also agrees with the Secretary's comments accompanying the release of the Final Rules that transplant professionals must make medical decisions. However, Gift of Life is concerned that while that may be the Secretary's intent, it is not a position reflected in the Final Rules. The Secretary continues to hold unilateral decision making on the content of policies, which should be determined by the medical community.

Although the Secretary points to the Advisory Committee on Organ Transplantation established under the Final Rules as the expert body that will be providing her with the medical science expertise on proposed allocation policies, she continues to make all final decisions and need not accommodate the directives of this body. We feel this may be redundant as the expertise already exists within the OPTN and its committees. Moreover, it is interesting that the OPTN Contractor Board and membership is to be comprised of representatives and persons knowledgeable in the field. No where in the Final Rules is there criteria regarding the composition or qualifications of members of the Advisory Committee. Its oversight function is lim-

ited in that while the Final Rules provide that "the Secretary will refer significant proposed policies to the Advisory Committee. . . .", and "may" seek the advice of the Committee on other proposed policies, the Secretary is not required to adhere to the advice of the Committee or make changes upon the Committee's recommendation. In fact, that section of the Final Rules which provides for the establishment of the Advisory Committee does not even require the Secretary to obtain the Committee's input, but instead provides that the Secretary "may seek the comments of the Advisory Committee on proposed OPTN polices".

Consequently, on this important issue it appears that the Final Rules continue to confer upon the Secretary the unilateral authority to establish policies impacting transplantation. This is inconsistent with the intent of Congress when it enacted the National Organ and Transplantation Act ("NOTA").

OPO performance criteria

The Preamble to the Final Rules highlights the issue of OPO performance, an issue that has also been the subject of extensive debate. The Preamble recommends that incentives be developed to reward "high performing OPOs". Gift of Life believes that OPOs should be held accountable to the patients and families they serve. However, performance criteria should be well defined and should measure more than the number of donors and the population base that an OPO supports. Until such time as criteria are well defined and validated, no action to decertify an OPO should be taken with the possible consequence of disrupting the care of the families of donors and recipients. This view has been reflected in statements made by the President, as well as an amendment to the NOTA reauthorization bill. Just as the Administration has recognized that a dialogue with the transplant community is necessary before changes should be proposed or implemented, Gift of Life requests that the Administration establish a dialogue with the Association of Organ Procurement Organizations on the issue of OPO certification standards. Also, the Administration should issue further guidance to the transplant community as to what performance measures the Administration believes relevant and the types of "incentives" that are contemplated.

PUTTING PATIENTS FIRST: INCREASING THE ORGANS AVAILABLE FOR TRANSPLANTATION

The federal government must continue to support efforts to increase organ and tissue donation in this country. It is only by increasing the number of organs and tissues that are donated that we can reduce the number of people that die or suffer needlessly while awaiting transplant. Monies must be provided to support donor education and awareness programs.

Earlier this year, I testified before the Commerce Committee of the U.S House of Representatives at a hearing entitled "Putting Patients First: Increasing Organ Supply for Transplantation". It has been the experience of Gift of Life that repeated and focused educational programs will increase donor awareness and will increase the number of organ donors. In Pennsylvania, between the years of 1995 and 1999, the actual number of donors that Gift of Life coordinated increased by 65 percent. Similarly the number of actual organ transplants that Gift of Life coordinated was 70 percent greater than the number Gift of Life coordinated in 1995. This growth occurred at a time when organ donations nationally increased an average of less than 2–5 percent a year.

This increase followed the enactment by the Pennsylvania legislature of a comprehensive donor awareness and education bill referred to as Routine Referral legislation. The Routine Referral legislation, among other items, requires that all hospital patient deaths be referred to the OPO for a determination regarding suitability and that all families of potential donors be advised of the donor option. Federal rules, modeled after this Pennsylvania law and our experience with the law, began being implemented nationally in August 1998. It is applicable to all Medicare and Medicaid participating hospitals. Preliminary data reveals that national organ donation rates for calendar year 1998 were 5.3 percent higher than donation rates for calendar year 1997. Likewise, in 1999, I suspect that the rates might have been even higher but for the continued public controversy regarding allocation.

Expanded public education programs, combined with best practices in hospitals can lead to increased consent rates. Even with the growth in donation experienced in Pennsylvania, Gift of Life along with CORE, the OPO serving the western half of the state, are working with the state Department of Health and Transportation on new initiatives to heighten awareness and increase donation. Captioned "Wanna make your license look great?", this new multi-media public education campaign encourages Pennsylvanians to elect the donor designation on their drivers' licenses. We believe that continued focused attention on this issue will lead to increased donation.

However, we will not be as successful if the current controversy is continued. The current system is not broken and does not require an overhaul. We must ensure that we continue the national public service and education programs designed to make citizens aware of the "Gift of Life" that is theirs to give. We also must safeguard the gifts of life that have already been made and not further harm public trust in the existing system. It is not "red, tape" that prevents patients from getting needed transplants, rather the organ donor shortage, which must be addressed by increased public awareness and education.

WAITING LIST GROWING

Senator SPECTER. Senator Santorum and I will begin with 5-minute rounds, and we may have more than one, depending upon how the Q and A goes, and I would begin with your final point, Mr. Nathan, about trying to get more organ donations.

The statistics show that the number of patients awaiting transplantation has grown from about 14,000 in 1988 to some 66,000 persons on waiting lists for organ transplantation today. What is your suggestion, Mr. Nathan, as to how we might stimulate more donations?

Mr. NATHAN. Well, I think three ways. One is to make sure that the Federal regulations for routine referral in all hospitals in the country are followed by every hospital in the country to see organ donation as a priority, so that every time an individual dies in this country, that person, the first question that is posed to that person's family is, was that person an organ donor. We think that that has to continue to be a priority, that HCFA must make sure that that is occurring in hospitals across the country in partnership with the OPO's.

Senator SPECTER. Can you give us your next two as briefly as you can? I want to move on with the questions.

Mr. NATHAN. Sorry. The second has to do with more awareness. I'm also president of the National Coalition—there's a campaign called, Share Your Life, Share Your Decision, and we believe that money has to be given to promote this, and market this as a cause that is important to citizens of the country.

I think last, the last surrounds having families think about this before it becomes an issue in their lives, and that also surrounds public education, so we do approach families.

Senator SPECTER. Dr. Raub, Mr. Nathan raises an objection which has been heard broadly. Quite a number of my colleagues wrote me objecting to the Secretary's regulations on the ground that she had unilateral authority.

One reading of the statute is that the Secretary's regulations are guidelines but UNOS is going to have the final say. The United Network for Organ-Sharing will come forward with a plan, and that that will be the final determinant. Actually, what will happen under the existing legislation as you see it?

Dr. RAUB. What we have tried to capture in the rule is the opportunity for the Organ Procurement Transplantation Network to come forward with its proposal for how organs would be allocated, first livers, and then all of the others. We want to rely very heavily on the medical judgment that we believe will be——

Senator SPECTER. Is that from UNOS?

Dr. RAUB. UNOS is the contractor, yes, sir.

Senator SPECTER. If they come forward with a plan, is that binding on the Secretary?

Dr. RAUB. No, it is not binding on the Secretary. It will be subject to review at the Department. We are hopeful that the plan will be responsive to the principles in the regulation.

Senator SPECTER. Does the Secretary then have the authority to veto the UNOS plan and establish whatever plan she unilaterally wishes?

Dr. RAUB. In theory, yes, sir, but in practice that is not the way the Secretary would do it. If she were unhappy with the plan submitted, she would indicate that to the contractor and any problem she has with it, and ask them to address it again.

Senator SPECTER. Well, that is an issue which I think we need to focus on, as to how we develop that. If you have ultimate authority in the Secretary, and final say, it raises a lot of hackles, and understandably so.

If there are some guidelines—and I do not have the magic formula at my finger tips, but I think it is something we need to grapple with so that it is ultimately a medical decision, perhaps some vast abuse of discretion, or some standard of review, but I would like you to transmit that concern to the Secretary. Senator Santorum and I doubtless will, too.

Before my yellow light expires, Dr. Reyes, let me take up a question with you, and that is this issue on timeliness that Mr. Nathan raises. Timing is everything. I recall perhaps the most famous transplant of all, which occurred right here in Pittsburgh for Governor Casey on June 14, 1993, a day I remember very well.

I had a problem of my own that particular day, and it was a magnificent double transplant, and Governor Casey has done remarkably well, although I think it not inappropriate to note that he is not feeling too well at the moment. Our thoughts and prayers are with him. Governor Casey testified at a field hearing we had on September 12 last year to get his views on transplant.

What is the reality on the objection raised by some as to the time limits, as to how long you can keep a liver or other organs viable?

Dr. REYES. Mr. Nathan's observation was based upon a donor that was 80 years old, and I believe that that is a fair observation, where if you have an older donor, or a donor from what we call an expanded pool that are very unstable, that you would qualify as poor donors, that is not the type of organs that you want to keep in preservation solutions for 16 hours.

The ideal donors, which is hard to define, are donors that are younger, that are very stable, and that at the time the organs are removed, the liver looks good.

Senator SPECTER. Under best condition, how long would the liver last?

Dr. REYES. 16 hours. I feel comfortable with 16 hours. I can get a liver into anybody from any organ procured anywhere in Canada within 16 hours.

Senator SPECTER. Thank you very much.

Senator Santorum.

Senator SANTORUM. Thank you very much, Mr. Chairman. Several questions. When was NOTA passed? What year was it passed?

Dr. RAUB. 1984.

Senator SANTORUM. How many centers were doing transplants in 1984, do you have any idea?

Dr. RAUB. Not off-hand, sir. A few dozen.

Senator SANTORUM. How many are doing it now?

Dr. RAUB. Over 200.

Senator SANTORUM. Under NOTA when there were only a few centers, all of those centers were given a voice in UNOS, correct, and now with 200-plus centers, all of them are given equal voice in UNOS, right?

Dr. RAUB. They all have a voice.

Senator SANTORUM. What was the survival of an organ outside, that was harvested in 1984, a liver, do you know?

Dr. REYES. It was about 60 percent survival.

Senator SANTORUM. I am talking about the liver. How long could it be preserved?

Dr. REYES. Less than 8 hours.

Senator SANTORUM. The point I want to make with that sort of fact scenario is, this is a very different world today, and we have a law that is outdated, and we allocated in the Congress to a group of hospitals, UNOS, basically a group of transplant centers an authority that we would never, never have done if there were 200-and-some today.

We would never have passed a UNOS today, and so I, too, have concerns about the Secretary's authority, and that has been the greatest complaint that I have heard, and I am not an ends-justifies-the-means kind of guy, so I still have those concerns.

I recognize why she is doing what she is doing, because the world has changed dramatically since 1984. When you harvested an organ in 1984, one of the reasons there was geographic sharing is because you could not send an organ very far, and so you had to share geographically.

Now that is not the case, but we have not really changed the rules to reflect the transition in technology, and to sort of rely upon that and saying, well, we have to keep it in place because that is the way we have done it, does not make a whole lot of sense to me when the world has changed.

The other thing is—and Mr. Nathan, I am not questioning anybody's motivations, but I think economic survival is a big issue in this arena for a lot of centers, and to me, that cannot be an issue. That just cannot be an issue.

What has to be the issue here is how we best allocate a very scarce resource, and I understand the complaints about the Secretary's authority, but the reason the Secretary is claiming this authority is because a system that has become so decentralized with so many voices from so many minor players representing their economic interest has destroyed the integrity of the system, and so that is why she has asserted her authority, and frankly we should have done so years before, and we have failed to do it.

Now, that does not in my mind—and I agree with Senator Specter, that does not give the Secretary license to do what may be the right thing, but questioning whether that is the right legal thing to do, but I certainly sympathize with what she believes is the need to do it.

I would just hope we have the courage in the next Congress and in this Congress coming up next year to take back the system of organ allocation and give it to who it belongs to, which is in this case the Government, and not a group of private transplant centers all over the country.

They should not be allocating—I disagree. They should not be allocating, because it has turned into too much of an economic football, and we cannot have a system that has public mistrust based on economics on such an issue that is too critical to be put in that category.

Now, having said that, I keep looking at your testimony here, Mr. Nathan, and it keeps coming back to the same thing. You have a problem with the Secretary's unilateral authority. I keep talking to my colleagues, and one of the things I keep hearing, particularly from my conservative brethren, is, we do not like the fact that Secretary Shalala is just taking something that is not in the law and doing it.

What I do not see, in all candor, here is really any problem with a lot of the substance of what she is doing. I do not—I mean, you are nit-picking here a little bit on substance. That is what it looks like to me, and correct me if I am wrong here, but when you pull out an 80-year-old donor and say, that is my problem, that is nit-picking a little bit.

Dr. Raub, excuse me, is there enough flexibility in this regulation to take care of the 80-year-old donor problem?

Dr. RAUB. Yes, sir, there is.

Senator SANTORUM. I think there is, and so you also say that broader regional sharing to provide for the transplant of the sickest patients first might result in adverse patient outcome and survival rates. The Institute of Medicine did not say that. Dr. Reyes, did they say that?

Dr. REYES. No.

Senator SANTORUM. There really are not any facts out there that suggest that is the case. I mean, you say we should listen to this. Well, OK, we will listen to it, but unless you have any facts to suggest that there is something here that is real, again, it is sort of throwing some flags up, but what you keep coming back to in every area is, you just do not like the Secretary telling you what to do. OK, but let us just be honest that that is what the issue is here, that is all.

Mr. NATHAN. The reality is I want the focus to be on donation because that is what I do, and because we are the ones who are facing the families, and we have to tell them the system is fair, it does work on behalf of patients.

Our concern is, and my coordinator's concern is that when they talk to families, there is concerns when it is on the front page of the paper that the Federal Government is going to revamp the system because it is unfair. I do not believe it is unfair.

I have been on the board of UNOS three different occasions. I participated on almost every committee. Although it is the medical community, half the membership of UNOS are public members. There are more than 480 voting members. Half of them are not transplant centers, and there are patient committees and minority committees to talk about these issues, and so I feel there has been

healthy debate, including from Pittsburgh. I think they clearly were listened to.

Senator SANTORUM. They are usually pretty quiet, so that is sort of surprising. [Laughter.]

Mr. NATHAN. Not behind the scenes, so there are some things that I agree with and some things I disagree with. The primary one was having a group of people who truly understand the dynamic system that occurs, because it is constantly changing. If somebody told me 10 years ago we were going to remove organs from an 82-year-old, I would have laughed.

When I started the donor age was 45. I just turned 46, so I would have been too old to be a heart donor 10 years ago, and so it is a dynamic process, and the medical people have to get it straight, to meet behind the scenes to make sure the system is fair, and certainly that the Government has to bless it but not necessarily override it.

Senator SANTORUM. I know my time has expired, but I agree with you that the issue has to be—and I always mention in every talk I ever give on this issue that this would not be a serious issue if we had enough organ donors.

I mean, I always bring out my little license here and my little green stamp underneath my picture that says organ donor, and I always ask everybody else to take out their wallets and show me whether you are an organ donor or not, and if you are not, do something about it, because there is no reason you should not be.

So I agree with you, and I think it is important to do it.

Mr. NATHAN. Those are the kinds of systems that I am begging people to set up in other States. Take a model—that that registry has 3.2 million people on the registry. It is the second highest in the country. If other States would start to do this, those places where there are these problems with sharing, they have problems with sharing but the reason why is their donor rates are not as large. They need to do more things to increase donations.

Senator SPECTER. Thank you, Senator Santorum. That is an easier question which Senator Santorum just articulated, when we ask someone to take out their wallet, than others might pose under analogous circumstances, just seeing the organ donor on their driver's license.

You had your hand up, Dr. Raub.

Dr. RAUB. May I comment further about the Secretary's role? A few points. One, the Secretary does not intend to practice medicine, and we all believe that if a future Secretary did, a future Congress would not allow that to happen, so we believe the rule in fact has the basic protections in it.

Second, the rule has performance criteria these proposals from the community need to meet.

Third, the amended rule includes a new advisory committee that in the open light of day would be a forum where experts could consider the proposals from the transplant community, and there would also be an oversight and critique on any judgment by the Secretary, and so we think we have built-in significant protections to ensure there is not arbitrary or capricious or uninformed action by the current Secretary.

Senator SPECTER. We want to move on to the next panel, but let me just raise one other question, or get an amplification on the question, and that is what Dr. Reyes has emphasized, and Mr. Nathan now says we have a fair system. When I look at these statistics on availability, or average waiting time on the liver transplant, Massachusetts 569 days, Kansas 12 days, Pennsylvania sixth to longest waiting period, 237 days, how about the basic issue of fairness, Mr. Nathan, in terms of those statistics?

Mr. NATHAN. When you take those apart, Senator Specter, the reality is, when you look at the most urgent patients, the Status 1 patients, and even the Status 2A's, which are the most urgent people, the people who are in danger——

Senator SANTORUM. Which you have not regionally adjusted. You have not done that with the 2A's.

Mr. NATHAN. That is correct. I do not disagree with you, Senator. That may be something that is the next step we have to talk about. When you take those apart, Senator, the waiting times do not differentiate that much between region to region, or OPO to OPO.

The waiting times begin to spread out when you get to the less critical people, and because of how people list patients, because of prior systems that have now been, I think, corrected, and Jorge may agree with me that the listing criteria when someone is placed on the list has changed, such that you do not put someone on the waiting list 5 years before they need a liver transplant.

Some of those days' waiting that you have said have a lot to do with those people who are not critically ill. They may need a liver transplant at some time, but they are not in danger of dying, and if you look at the most critically ill patients, which has been the argument, there is not that much difference in the waiting time.

Clearly, people die, no question about it, and we have to stop that, but I am not sure, and I have not been convinced yet that national sharing, for example, would solve that problem.

Senator SPECTER. Dr. Reyes, Mr. Nathan says he hopes you agree with him.

Dr. REYES. I disagree. For the Status 1's and the Status 2 there really is a significant difference in waiting time, and I have some recent statistics that for Status 1 the minimum time is 2 days and the maximum time 16. For Status 2, the minimum time goes from 7 to a maximum time of 71 days.

Now, depending on why the patient is in the hospital, those days can make a big difference. Right now, I have in our intensive care until at Children's Hospital one boy that has been waiting for 2 weeks as a Status 1 for an organ, and another boy that has been waiting for a month as a Status 1 for an organ, and so there are significant differences.

Senator SPECTER. It would be useful, I think, to this subcommittee and to the Senate and the House generally to really get some finite statistics which bring the distinctions which you raise, Mr. Nathan and Dr. Reyes, because we need to be informed with precision as to the various classifications. When I look at the various categories in the lifetime and the complexities here, that needs to be front and center before we take up these issues.

A final comment, Dr. Raub.

Dr. RAUB. Just another fact related to that. The differences in categories 1A and 2A for livers cannot be very long, because one has to have 7 days estimated to live to be in that category. So, by the nature of the system, it would be a much smaller zone than would be true for the other categories.

Senator SPECTER. Well, as that impacts on the people in the longer period, we need more information as to what category these 569 people in Massachusetts, on their waiting, and maybe they cannot have that for aggravated liver problem, the people in Kansas. Kansas until not too long ago was a dry State. [Laughter.]

Senator Santorum.

Senator SANTORUM. No further questions.

Senator SPECTER. OK. Thank you very much, Dr. Raub, Mr. Nathan, Dr. Reyes. We appreciate your being with us.

We now want to turn to panel 2, and our witnesses are Mr. Cleo Gilmore, Dr. Warren Hulnick, and Mr. David Somerville.

STATEMENT OF CLEO GILMORE, YEADON, PA

Our first witness is Mr. Cleo Gilmore from Yeadon, Pennsylvania, a former sales executive for Ortho McNeil, a division of Johnson & Johnson. He has been listed and treated for liver disease at the University of Pittsburgh Medical Center, but at UPMC's urging he was also placed on the organ waiting list at the University of Miami and was able to get his transplant there. He is a graduate of Penn State and married with one child.

Mr. Gilmore, thank you very much for joining us, and the floor is yours, and if you could summarize within 5 minutes, we would appreciate it.

Mr. GILMORE. Thank you, Mr. Chairman. In 1994 I was diagnosed with primary sclerosing cholangitis. That was the same fatal disease that recently took the life of football great Walter Payton. Fortunately, my fate was different than that of Mr. Payton's. After a long and difficult road, I received a liver transplant at Jacksonville Memorial Hospital in March of 1996.

When I was first diagnosed, I was getting my care at one of the local transplant centers in Philadelphia. It was not long before my condition started to worsen, and in November of 1995 I ended up in the hospital for over 3 weeks. In January of 1996, my doctors in Pennsylvania began to get very concerned about my condition. They did not think that they would be able to find a donor liver in time to save my life, so they suggested that I contact the University of Miami, because they had a shorter waiting list.

At my own expense, I flew to Miami to be evaluated for transplant. I was immediately put on the Miami transplant list and sent back home to Philadelphia with my pager. Now, I was on two lists, two transplant lists, one in Pennsylvania and one in Florida.

Sure enough, a few weeks later a donor liver was found for me in Florida, and once again at my own expense I chartered a plane to Miami to receive my liver transplant. The cost for that flight was $8,000. Despite having excellent insurance coverage, I was deeply in debt following my transplant just because of the travel expenses alone.

My story is not unique. There are many patients across the country who go to great lengths and expense to find a donor organ. Un-

fortunately, there are many, many more patients who lack the resources to double-list or to shop for shorter waiting lists like I did. If you do not have the resources, then you are at the mercy of the transplant system.

I was fortunate. The fact is that the current transplant system is not fair. In my case, I was on two waiting lists at two different hospitals. When the liver was found in Miami, why couldn't they just send it up to me in Pennsylvania, instead of forcing me to leave my family and my support system in Philadelphia? It is just not fair.

Mr. Chairman, I know you have been working hard to change the system, and I appreciate your efforts. The last time I spoke about this issue was in 1996, at a 3-day hearing conducted by the Department of Health and Human Services. I was one of over 100 witnesses.

Since then, I understand that the HHS has received thousands and thousands of comments on this issue. I think the Secretary has done a very good job responding to those comments, and I support the HHS transplant regulations. They will ensure that all patients have a fair and equal chance of finding a donor organ, and that donated organs will go to the patients who need them the most.

A person should not get a transplant just because they live close to the donor. In my case I would have gladly waited longer if somebody sicker than me needed the organ more. We all have to wait our turn, but it was very frustrating to sit and wait while healthy people get transplants and I was so close to dying. The HHS regulations will make the transplant system fair for everyone.

But despite your efforts, Mr. Chairman, Congress has put the regulation on hold again for the third time, and it is clear to me the goal of UNOS and many members of the transplant community and some Members of Congress is to kill these regulations no matter how many lives it may cost in the long run.

The comment period has now gone on for 3 years since that first hearing. Now it is time to take action. The regulations' opponents have waged a successful propaganda campaign in order to make their case. However, this July the truth came out in the form of a report from the Institute of Medicine. The report was ordered by Congress last year. The IOM supported the HHS regulations and dispelled the myths that had been promoted by those opposing the regulations.

One of the claims that opponents make is that the HHS regulations will make it difficult for minorities and low income patients to access the organ transplant system. The IOM found no evidence to support that claim. As my story shows, it is those patients with limited resources who have a difficult time getting transplants. Many of those patients are inner city minorities.

I was able to get a liver transplant because I had the resources to escape the discrimination that rules our organ transplant system. If I was not able to pay for a charter flight to Florida, I might not be here today.

It is well-documented that African Americans wait nearly twice as long as whites for kidney transplants. This is not fair. Some of the reason for this difference is biological, but a change in the allocation system could even out the playing field dramatically.

I believe that a fair system based upon the broad sharing of donated organs is what Congress intended when it started this program 15 years ago. That goal can only be achieved if the regulations are allowed to go into effect.

Now, in addition to trying to kill these regulations, some of your colleagues in Congress have introduced a bill to rewrite the transplant act. The impact of this bill is frightening to me. Not only would the bill cripple the Secretary, it would also ensure that the very organization that created this poorly run system, the same organization that has spent millions lobbying against the HHS regulations, would be guaranteed the network contract forever.

PREPARED STATEMENT

Mr. Chairman, I encourage you to keep up the good fight. As you can see today, patients and professionals from both sides of the State of Pennsylvania support your efforts to change the system. I hope you will do everything you can do to implement these regulations in addition to stopping efforts like the OPTN amendments that would cripple the transplant system.

Thank you for holding this hearing today.

Senator SPECTER. Thank you very much, Mr. Gilmore, for testifying about your situation. It is very important.

[The statement follows:]

PREPARED STATEMENT OF CLEO GILMORE

Thank you, Mr. Chairman. In 1994 I was diagnosed with sclerosing cholangitis—the same fatal disease that recently took the life of football great Walter Payton. Luckily, my fate was different than Mr. Payton's. In March of 1996 I received a liver transplant at the University of Miami Jackson Memorial Hospital. However, the road from when I was diagnosed to when I received my transplant was a long and difficult one.

When I was first diagnosed, I was getting my care at one of the local transplant centers in Philadelphia. It wasn't long before my condition started to worsen and in November 1995 I was referred to the University of Pittsburgh Medical Center. I ended up in the hospital for over 3 weeks. In January of 1996, my doctors in Pennsylvania began to get very concerned about my condition and didn't think that they would be able to find a donor liver in time to save my life. So they suggested that I contact the University of Miami because they had a shorter waiting list.

At my own expense, I flew to Miami to be evaluated for a transplant. I was put on the Miami transplant list and sent home to Philadelphia with my pager. Now I was on two transplant lists—one in Pennsylvania and one in Florida. Sure enough, a few weeks later a donor liver was found for me in Florida and, once again at my own expense, I chartered a plane to Miami to receive my liver transplant. The cost for that flight was $8000. Despite having excellent insurance coverage, I was deeply in debt following my transplant just because of the travel expenses alone.

My story is not unique. There are many patients across the country who go to great lengths and expense to find a donor organ. Unfortunately, there are many, many more patients who lack the resources to double list or to shop for shorter waiting lists. If you don't have the resources then you are at the mercy of the transplant system.

The fact is that the current transplant system is not fair. It is designed to favor those transplant centers with political clout while forcing patients like me to make huge sacrifices or face certain death. In my own situation, I was on two waiting lists at two different hospitals. When the liver was found in Miami, why couldn't they just send it up to me in Pennsylvania instead of forcing me to leave my family and my support system in Philadelphia? It's just not fair.

Mr. Chairman, I know that you have been working hard to change the system and I appreciate your efforts. I am here today because I am very upset at the political games that are being played in Washington over this matter.

The last time I spoke about this issue was in 1996 at a three-day hearing conducted by the Department of Health and Human Services. I was one of over 100

witnesses. Since then, I understand that HHS has received thousands and thousands of comments on this issue.

I think the Secretary has done a very good job responding to those comments and being sensitive to all interests in the transplant field. I support the HHS transplant regulations. They will ensure that all patients have a fair and equal chance of finding a donor organ. The emphasis on medical need is also important. Donated organs should go to the patients who need them the most. A person shouldn't get a transplant just because they live close to the donor. In my case, I wouldn't have minded if I had to wait longer so that someone who was sicker than me could have gotten a transplant. We all have to wait our turn. But, it was very frustrating to sit and wait, or to go to great sacrifice and expense, while healthy people got transplants and I was so close to dying. The HHS regulations would make the transplant system fair for everyone.

But, despite your efforts, Mr. Chairman, Congress has put the regulations on hold again for the third time so that the public could comment on the newest revisions. I don't believe that Congress put the HHS organ transplant regulations on hold again in order to give people a chance to comment. It is clear from this patient that the goal of UNOS, many members of the transplant community, and some members of Congress is to kill these regulations no matter how many lives it may cost in the long run. The comment period has now gone on for three years since that first hearing. Now, it is time for action. And time for change.

In order to make their case; those opposing the transplant regulations have waged a successful propaganda campaign based on a number of misleading statements. Last year, when Congress delayed the regulations, a study was also ordered from the Institute of Medicine. The goal of that study was to find the truth.

This July, the IOM came out with its report. The IOM supported the HHS regulations and dispelled the myths that had been promoted by those opposing the regulations. One of the claims opponents make is that the HHS regulations will make it difficult for minorities and low-income patients to access the organ transplant system. The IOM found no evidence to support that claim.

As my story shows, it is those with limited resources, many of who are inner city minorities that cannot access the current system. I was able to get a liver transplant because I had the resources to escape the discrimination that rules our organ transplant system. If I wasn't able to pay for a charter flight to Florida I might not be here today.

It is well documented that African Americans wait nearly twice as long as whites for kidney transplants. This is not fair. Some of the reason for this difference is biological. But, a change in the allocation system could even out the playing field dramatically. The HHS regulations would require the network contractor UNOS to make necessary changes to the geographically based system that is currently in place and bring fairness back into the system. I believe that a fair system—based upon the broad sharing of donated organs—is what Congress intended when it started this program 15 years ago. That goal can only be achieved if the regulations are allowed to go into effect.

Now, in addition to trying to kill these regulations some of your colleagues in Congress are trying to make dramatic changes to the act that governs our national transplant system. The Organ Procurement and Transplantation Network Amendments of 1999 would take away any authority that the Secretary has to govern the transplant system. The impact of this bill is frightening to me. Not only would the bill cripple the Secretary, it would also insure that the very organization that created this poorly run system, the same organization that has spent millions lobbying against the HHS regulations, would be guaranteed the network contract forever.

Mr. Chairman, I encourage you to keep up the good fight. As you can see today, patients and professionals from both sides of the state of Pennsylvania support your efforts to change the system. I hope that you will do everything you can to implement these regulations. I also hope that you will do everything you can to stop efforts like the OPTN Amendments Act that would cripple the transplant system.

Thank you for holding this hearing today. There are almost 70,000 people now waiting for organ transplants in this country who are hoping that Congress will do the right thing in this debate. Mr. Chairman, I know you will continue your efforts to steer your colleagues in the right direction. Thank you.

STATEMENT OF DR. WARREN D. HULNICK, TRANSPLANT RECIPIENTS INTERNATIONAL ORGANIZATION

Senator SPECTER. We turn now to Dr. Warren Hulnick, a retired dentist who received a liver transplant at the University of Pittsburgh Medical Center. He has been a patient advocate for many

years, and he is past president of the Pittsburgh Chapter of the Transplant Recipients International Organization.

He earned his dental degree from NYU and two master's degrees from the University of Pittsburgh. Welcome, Dr. Hulnick. We look forward to your testimony.

Dr. HULNICK. Thank you, Senator. Thank you for allowing me to present my views on the current situation in organ allocation and for your hard work on this contentious issue. I also want to thank Senator Specter and the committee for holding this hearing today.

I am a 58-year-old liver transplant recipient. I received my transplant at the University of Pittsburgh Medical Center almost 13 years ago. Prior to my surgery, I was a dentist practicing in Staten Island, New York. After my transplant I moved to Pittsburgh and obtained MBA and MHA degrees and worked as an independent contractor at the Graduate School of Public Health. I am currently retired.

I am a member of TRIO, the Transplant Recipients International Organization, and past member of its international board of directors, and past president of the Pittsburgh Chapter. I currently serve as the appointed U.S. Region 2 representative to the Patient Affairs Committee of UNOS. I also volunteer at the Thomas E. Starzl Transplant Institute, working mostly with liver transplant candidates. It is from these several viewpoints that I speak today.

In January 1987, when I received my transplant, donated organs were given to the most medically needy patient within logistical limits. The liver I received was recovered in Alabama. With the geography-based allocation system in place today, I might not have survived the wait. There were no arbitrary boundaries for organ placement, and the system functioned smoothly.

While it is true that there are more transplant programs in existence today, in theory patients should receive organs according to medical necessity, but that is not the case. When an organ is donated, it is not donated for the benefit of a particular geographic area or OPO or transplant program, but it is to benefit the most medically needy patient.

I feel the position taken by Secretary Shalala that donated organs need to be offered to the most medically needy patients within acceptable limits is correct and equitable. To me, there is nothing illogical about sending a liver to a Status 1 or Status 2A patient, those considered the sickest, 1,000 miles away, rather than transplanting it to a Status 3 patient living in the local area where it was recovered. That Status 3 patient is not in urgent need of transplantation. However, the allocation system currently in place encourages this type of activity.

My view is also shared by TRIO. TRIO is a nonprofit organization. Its membership includes transplant recipients, candidates and their families, donor families, medical professionals, and others interested in organ and tissue transplantation.

Much of TRIO's activity is centered around advocacy for transplant-related issues, and the education of the public about transplantation and organ donation. TRIO as an organization has strongly supported the Secretary's proposed rule changes because they benefit patients, not organizations. The system of organ allo-

cation needs to be patient-driven, not for the benefit of transplant centers.

As a member of UNOS's Patient Affairs Committee, I have seen what I feel is an attempt to reduce patient input in the affairs of UNOS. According to the orientation booklet given to all committee members, and also what UNOS tells the public and the media, and I quote: "the Patient Affairs Committee is charged with advising the UNOS board of directors and other committees about patient and donor family perspectives on proposed policies and issues."

At the meetings, the atmosphere is quite different. Both the committee chair and the cochair are appointed by the UNOS president, not chosen by committee members. To me, this is rather undemocratic and can serve to spin the agenda away from issues and discussion contrary to the UNOS's stated or preferred policies.

Frequently, UNOS staff members are present, not to provide support to the committee, but to participate in and frequently dominate discussion. I feel that their presence is a hindrance to free and open discussion. I found the situation so uncomfortable that I felt it necessary to inform Secretary Shalala that many patients do not have a voice under the current system. I offer this letter and the HHS response to me for the record.

Senator SPECTER. It will be admitted. Thank you.

Dr. HULNICK. In my contacts with potential liver transplant candidates, many with little knowledge of what they are becoming involved in, there is an enormous need for an easy-to-access, current, correct, understandable information about liver transplantation, the most frequently asked questions involve hospital length of stay, cost, ability to return to normal life and, of course, survival rates. Increased efforts must be made to provide this information.

Over the last year, too, more patients are asking questions involving allocation. Many are afraid that without a change in the allocation system they will not survive long enough to receive a transplant because of the long waiting list.

At UPMC, many patients are from outside the Pittsburgh area, enlarging the list, yet with the current system, if they receive a transplant the liver would most likely come from Western Pennsylvania. This, in turn, disadvantages local patients, since the donor pool is shared with these outsiders.

If one were to look at the patient populations at the centers who are seeking to keep the allocation system local, most likely the large percentage of patients would be local also. This is totally unfair. Organs should go to those in most need, no matter where the patient is. They should not go to patients based on where the organ is recovered.

In closing, I would say we need to make the organ allocation system patient-driven. Organ transplantation must be removed from corporate profits and returned to medical practice as soon as possible, because too many lives are being unnecessarily lost with the current system.

PREPARED STATEMENT

As we all know, increasing organ donation would help alleviate the problem, but until we can recover enough organs for everyone on the waiting list, we must work with what is available and make

it operate to its maximum efficiency. Thank you for this opportunity.

Senator SPECTER. Thank you, Dr. Hulnick, for giving us your views.

[The statement and letters follow:]

PREPARED STATEMENT OF DR. WARREN D. HULNICK

Senator Specter, Senator Santorum: Thank you for allowing me to present my views on the current situation in organ allocation and for your hard work on this contentious issue. I also want to thank Senator Specter and the Committee for holding this hearing today.

I am a 58 year old liver transplant recipient. I received my transplant at UPMC almost 13 years ago. Prior to my surgery I was a dentist practicing on Staten Island, NY. After my transplant I moved to Pittsburgh, attained MBA and MHA degrees at Pitt, and worked as an independent contractor at the Graduate School of Public Health. I currently retired.

I am a member of TRIO, the Transplant Recipient's International Organization, a past member of its International Board of Directors and Past-President of the Pittsburgh Chapter. I currently serve as the appointed UNOS Region 2 representative to the Patient Affairs Committee of UMOS. I also volunteer at the Thomas E. Starzl Transplant Institute of UPMC working mostly with liver transplant candidates.

It is from these several viewpoints that I speak today.

In January 1987, when I received my transplant, donated organs were given to the most medically needy patient, within logistical limits. The liver I received was recovered in Alabama. With the geography based allocation system in place today, I might not have survived the wait. There were no arbitrary boundaries for organ placement and the system functioned smoothly. While it true that there are more transplant programs in existence today, in theory patients should receive organs according to medical necessity. But that is not the case. When an organ is donated it is not for the benefit of a particular geographic area or OPO or Transplant Program, but it is to benefit the most medically needy patient. I feel the position taken by Secretary Shalala, that donated organs need to be offered to the most medically needy patient within acceptable limits is correct and equitable. To me, there is nothing illogical about sending a liver to a Status 1 or Status 2A patient—those considered the sickest—1,000 miles away, instead of tranplanting a Status 3 patient living in the local area where it was recovered. The Status 3 patient is not in urgent need of transplantation. However, the allocation system currently in place encourages this type of activity.

My views are also shared by TRIO. TRIO is a non-profit organization whose membership includes transplant recipients, candidates, their families, donor families, medical professionals and others interested in organ and tissue transplantation. Much of TRIO's activity is centered around advocacy for transplant related issues and education of the public about transplantation and organ donation. TRIO has strongly supported the Secretary's proposed rule changes because they benefit patients not organizations. The system of organ allocation needs to be patient driven, not for the benefit of transplant centers.

As a member of UNOS' Patient Affairs Committee I have seen what I feel is an attempt to reduce patient input in the affairs of UNOS. According to the Orientation Booklet given to all committee members and also what UNOS tells the public and the media: "The Patient Affairs Committee is charged with advising the UNOS Board of Directors and other committees about patient and donor family perspectives on proposed policies and issues. . . ." At the meeting the atmosphere is quite different. Both the Committee chair and co-chair are appointed by the UNOS Board not chosen by committee menders. To me this is rather undemocratic and can serve to "spin" the agenda away from issues and discussion contrary to UNOS' stated or preferred policies. Frequently UNOS staff members are present, not to provide support to the committee but to participate in and frequently dominate discussion. I feel that their presence is a hindrance to free and open discussion. I found this situation so uncomfortable that I felt it necessary to inform Sec. Shalala that many patients do not have a voice under the current system. I offer this letter and the HHS response to me for the record.

In my contacts with potential liver transplant candidates, many have little knowledge about what they are becoming involved in. There is an enormous need for easy-to-access, current, correct, understandable information about liver transplantation. The most frequently asked questions involve hospital length of stay, costs, ability

to return to normal life and of course survival rates. Increased efforts must be made to provide this information. Over the last year or two, more patients are asking questions involving allocation. Many are afraid that without a change in the allocation system they will not survive long enough to receive a transplant because of the long waiting list. At UPMC, many patients are from outside the Pittsburgh area, enlarging the list. Yet with the current system, if they receive a transplant, the liver would most likely come from Western Pennsylvania. This in turn, disadvantages local patients, since the donor pool is shared with "outsiders". If one would look at the patient populations at the centers who are seeking to keep the allocation system "local, most likely the large percentage of patients would be "local" also. This is totally unfair. Organs should go to those in most need, no matter where the patient is; they should not go to patients based on where the organ is recovered.

In closing, I would say we need to make the organ allocation system patient driven. Organ transplantation must be removed from "corporate profits" and returned to medical practice as soon as possible because too many lives are being unnecessarily lost with the current system.

As we all know, increasing organ donation would help alleviate the problem, but until we can recover enough organs for everyone on the waiting lists, we must work with what is available and make it operate to its maximum efficiency.

Thank you again for this opportunity.

LETTER FROM DR. WARREN D. HULNICK

WARREN D. HULNICK, D.D.S.,
Pittsburgh, PA, April 5, 1999.

Hon. DONNA E. SHALALA, Ph.D.,
Secretary, U.S. Department of Health and Human Services,
Washington, DC.

DEAR SECRETARY SHALALA: I am the representative from Region 2 to the United Network for Organ Sharing (UNOS) Patient Affairs Committee and a liver transplant recipient of more than 12 years. As such, I must express my concern with the method with which this Committee operates, especially on matters involving the organ allocation controversy. Discussion is controlled by the appointed committee chair and/or vice-chair, who both follow the UNOS party line in opposing your efforts of reform. Members who are known to hold differing views are often not recognized or are cut short during discussions.

At our recent meeting (March 18–19), a member prepared a document (copy attached) for discussion that summarized the organ allocation controversy and called for several resolutions to aid in solving the problem. As the Chairman introduced the agenda item, he remarked that he sought to "frame the discussion" and mentioned that he had considered not placing the item on the Agenda at all. This statement essentially stifled any discussion.

According to the Orientation Booklet given to all committee members and what UNOS tells the public and the media: "The Patient Affairs Committee is charged with advising the UNOS Board of Directors and other committees about patient and donor family perspectives on proposed policies and issues. . . ." I fail to see how not placing an item on an agenda or stifling discussion because it espouses a contrary opinion aids in advising the Board of Directors, especially on controversial subjects.

I also find it unusual that UNOS staff are present at the meetings, not to serve as support personnel but to participate in and at times dominate discussion. Their presence is a deterrent to open and free discussion, as some Committee members take their opinion as official doctrine and appear to not wish to oppose them, perhaps in fear of losing their committee appointment.

I can offer no solution to the problems I perceive, except perhaps that a new organization, more attuned to the concerns of candidates, recipients and donor families rather than transplant centers, be selected to operate the Organ Procurement and Transplantation Network, or your Department increase its oversight authority to more closely supervise the operation of UNOS.

Very truly yours,

WARREN D. HULNICK, D.D.S.

Enclosure (1).

ORGAN ALLOCATION POLICY, THE KANSAS CITY DECLARATION

Whereas: The recently deadlocked negotiations between the Department of Health and Human Services (DHHS) and the United Network For Organ Sharing (UNOS)

have had a deleterious effect on the transplant community and the public at large, and

Whereas: The DHHS position, in the literal interpretation of its proposed transplant policy, imposes potentially non-medical, and potentially counter-productive protocols for the allocation of organs, i.e. The Secretary's rules and regulations, and unnecessarily politicizes what should be a primarily medically determined process, and

Whereas: The current localized policies promulgated by UNOS create unnecessary inequities in waiting time and in patient access to transplantation resulting in the public perception that the policy does not always serve the best interests of patients and the nation's public health, and

Whereas: The transplant community has made many revisions in its policies in recent years, thereby contributing to a sense of constant change and indecisiveness, and

Whereas: The current policies have led to fragmentation and the absence of consistent national standards as evidenced, for example, in the initiatives in a number of states to legislate a prohibition against organs leaving the political boundaries of the states e.g. (LA, AZ, etc.), and in the varying practices and standards across the country, and

Whereas: The professional transplant community with the best intentions and objectives has been unable to achieve agreement with DHHS on a medically driven sound and fair allocation system, and both realize it is in their best interest and in the best interest, especially, of patients to do so, and

Whereas: An effective, fair and credible system of allocation is essential to creating the public trust that will increase organ donation as the only ultimate solution to inequity, and

Whereas: The Immediate Past President of UNOS, Dr. Lawrence Hunsicker, in presentations across the country in 1998 urged the patient community to take the lead in facilitating the emergence of a national consensus on this issue, and

Whereas: The Patient Affairs Committee is best positioned in terms of broad representation of the diverse segments of the transplant community (donor groups, recipients, OPOs, transplant centers) and knowledge of the multiple factors effecting donation, allocation and delivery of solid organs,

Be It Resolved: The Patient Affairs Committee recommends that UNOS develop a new allocation policy for all organs based on the following principles.

1. All organs will be allocated to the patient who has accumulated the most amount of waiting time, whose medical status is highest for transplantation in keeping with the agreed upon listing and status criteria as overseen by the organ-specific regional review committees, and for whom the prognosis is positive.

2. Organs will be allocated to the patient who is listed at a center where the delivery of the organ is possible within medically established ischemic times, regardless of the location of the procurement.

3. That fluid and constantly changing regions, as determined by place of procurement, varying somewhat in size for different organs as ischemic times dictate, will require that the number of OPO's either be consolidated or organized in a collaborative structure to insure efficiency and eradicate unproductive competitiveness and duplication of effort.

4. That the number of licensed transplant centers be keyed to a minimum number of organ transplantations annually in order to insure maximum outcomes and adequacy of qualified staff.

5. That UNOS continue to rapidly facilitate the development and clear articulation of objective medical standards, insofar as possible, for the classification of patients in terms of illness and prognosis as well as in regard to safe ischemic times for transportation appropriate to specific organs.

LETTER FROM JOSEPH F. O'NEILL

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
HEALTH RESOURCES AND SERVICES ADMINISTRATION,
Rockville, MD, May 13, 1999.

WARREN D. HULNICK, D.D.S.,
Pittsburgh, PA.

DEAR DR. HULNICK: Thank you for your letter of April 5 to Secretary Shalala and the accompanying proposed resolutions to develop new United Network for Organ Sharing (UNOS) organ allocation policies. The resolutions discussed in the paper presented before the Patient Affairs Committee are noteworthy and support many of the concepts underlying the Department's Final Rule for the Organ Procurement

and Transplantation Network (OPTN). However, your letter raises serious concerns regarding the opportunity for open and free discussion of controversial issues brought before the Patient Affairs Committee. I have asked D.W. Chen, M.D., M.P.H., Director of the Division of Transplantation to discuss these concerns directly with UNOS, without identifying you or your committee, so that your role and activities within the Patient Affairs Committee would not be jeopardized.

One of the features of the Department's Final Rule for the OPTN, issued April 2, 1998, gives the Secretary authority to review complaints raised concerning OPTN policies. The Rule fully supports meaningful input from the members of the OPTN and other stakeholders in the development of OPTN policies. As stated in the Rule, "the Department believes that the transplantation network must be operated by professionals in the transplant community, and that both allocation and other policies of the OPTN should be developed in an open environment that includes the public, particularly transplant patients and donor families." This section of the Rule implies a very strong role for the Patient Affairs Committee in policy development. The Department supports and encourages open and constructive communication and debate on policy development, as well as other issues impacting the OPTN. Open forums and freedom to discuss differences of opinion freely, especially within UNOS Committee meetings, are critically important to addressing often complex and contentious issues within the OPTN.

As you know, the Omnibus Consolidated and Emergency Supplemental Act, 1999, has delayed the effective date of the Final Rule until October, at the earliest, and requires the Institute of Medicine (IOM), under contract with the General Accounting Office (GAO), to study organ allocation issues. The Department believes that the IOM and the Congress will recognize the necessity of the Secretary's authority to oversee OPTN policy development. However, until the final Rule becomes effective, HHS has limited ability to review alleged improper activities of OPTN members which may lead to complaints.

We would encourage you to discuss your perceptions with other members of the Patient Affairs Committee and work toward achieving a consensus view on this matter. Consensus building is the method by which UNOS policies are developed, and in order to create fair and objective policies, we need representatives from the patient community willing to speak out especially when contentious issues are discussed. Thank you for bringing this issue to the attention of the Secretary. We will address your concerns anonymously and directly with the appropriate representatives at UNOS. If you have any additional questions, please contact D.W. Chen, M.D., M.P.H., Director, Division of Transplantation, Office of Special Programs, Room 4–81, Rockville, Maryland; telephone number (301) 443–7577.

Sincerely,

JOSEPH F. O'NEILL, M.D., M.P.H.,
Director.

STATEMENT OF DAVID SOMERVILLE

Senator SPECTER. Our next panelist is Mr. David Somerville from Latrobe, PA. He suffers from an autoimmune disease that attacks the bile ducts and the biliary system. Mr. Somerville is listed as a Status 3 under the United Network for Organ-Sharing criteria. He and his wife of 31 years, Kathy, have three children.

He spent most of his career in community service. Most recently he worked as an insurance salesman. He was diagnosed with liver disease in 1993, and he now spends most of his time volunteering for the Center for Organ Recovery and Education.

Thank you for coming in today, Mr. Somerville, and we look forward to your testimony.

Mr. SOMERVILLE. Good morning, Mr. Chairman and Senator Santorum. Unlike my two predecessors that have spoken on this panel, they have received the gift of life. I am waiting for the miracle to occur yet. Thank you for the opportunity to testify today.

My name is David Somerville, and I am from Latrobe, PA. I am 51 years old, and I have primary sclerosing cholangitis, an autoimmune disease that attacks the bile ducts and biliary system. This is the same disease that claimed the life of pro football Hall of Fame legend Walter Payton.

I was diagnosed with this condition in 1993. Since then, and in the past 6 years I have been waiting for liver transplant at the University of Pittsburgh Medical Center. I am currently listed in the United Network for Organ-Sharing criteria as a Status 3.

For the better part of my life I worked in community service as a salesman for a large insurance company. In 1968 I married my college sweetheart, Kathy, whom I met at Lockheed University and enjoyed raising my three kids. For me, life was good, and in 1993 I started to feel something was not right. I went through a series of rigorous tests and was ultimately delivered the devastating news that I had liver disease. How could this happen to me? To be told that I could not survive without a transplant is inconceivable. In fact, in 1983 I had run a 26-mile marathon in Erie, PA.

When I was first put on the transplant list there were little symptoms of my disease, but the longer I remain on the list the symptoms get worse and continue to rob me of the life I once had. Living with liver disease is unpredictable. Recently, I have had to have my medications changed to manage my condition. It is a struggle every day, and I pray my waiting will soon be over.

While I have been on the waiting list for a long time, I am fortunate that the medical staff here at UPMC is able to manage my illness and keep my spirits up. I try to fill my time as best I can by volunteering with the local organ procurement agency, the Center for Organ Recovery and Education, CORE. I also am part of the local support group in Westmoreland County that meets once a month in Greensburg, PA. There are approximately 12 to 20 people at each meeting.

In the short time I have known these patients we have formed a bond that is unbreakable. Among this group I am in the minority. There are more patients waiting for hearts. Several of them are in worse shape than I am. It saddens me that they are the ones who end up not getting transplanted due to the lack of organs. In fact, 25 percent of patients waiting for hearts and lungs will never get that chance.

Our support group has seen first-hand the effects of this, and as much as I would love to get my liver transplant, I would gladly wait if I knew there were sicker people who needed it.

There needs to be a broader sharing of organs if people are to get a fair chance. The United Network for Organ-Sharing's first and last words are "United" and "Sharing." When you break those words down there are no regional boundaries. It is time to make organs available for everyone, no matter where they live. We need to put a human face on this issue. Too many people are dying needlessly. Please do your parts, Senator Specter and Senator Santorum, to make patients a priority in this debate.

While more work needs to be done on the legislative side, it is up to the rest of us to do our part. Many of you are well aware of the recent passing of football legend Walter Payton. If people do not know enough about the importance of organ donation before, they do now. We need to make sure that steps are being taken to ensure people sign an organ donor card so we will not have to hear about patients dying from the lack of organs.

Some people say organ donation is a personal choice, but I am challenging Americans to look at the big picture. Imagine if you

had a mother or father on dialysis for many years while waiting for a kidney transplant. Imagine if your child was born with a liver disease and needed a transplant to save his or her life. Would you not start thinking differently about organ donation?

There are currently 66,000 people on the UNOS waiting list. Think about that. That is enough to fill Three Rivers Stadium.

Yesterday, I spoke to some local high school students and encouraged them to become organ donors. It is my hope that they will make that personal choice.

As one of 66,000 waiting for a new chance at life, I am asking that the rest of you make that choice, for it can make those of us who are waiting very happy.

PREPARED STATEMENT

In conclusion, in putting a human face to this issue as one of 66,000 waiting, I am also a son, I am a husband, I am a father, I am a son-in-law, I am a brother, I am a brother-in-law, I am a nephew, I am an uncle, I am a cousin, and those are nine opportunities in my immediate family. Multiply that by 66,000, and we have a lot of people that are involved in this issue.

Thank you for the opportunity to speak.

Senator SPECTER. Well, thank you very much, Mr. Somerville. You have a great multiplication factor in terms of how many lives you are touching.

[The statement follows:]

PREPARED STATEMENT OF DAVID SOMERVILLE

Good morning, Mr. Chairman and Senator Santorum. Thank you for the opportunity to testify today. My name is David Somerville and I am from Latrobe, Pennsylvania. I am 51-years old and have primary sclerosing cholangitis, an autoimmune disease that attacks the bile ducts and biliary system. This is the same disease that claimed the life of Pro Football Hall of Fame legend Walter Payton. I was diagnosed with this condition in 1993. Since then, and for the past six years, I have been waiting for a liver transplant at the University of Pittsburgh Medical Center. I am currently listed under the United Network for Organ Sharing criteria as a status three.

For the better part of my life I worked in community service and was a salesman for a large insurance company. In 1968 I married Kathy Ritchie and enjoyed raising our three kids. For me, life was good. Then in 1993, I started to feel something wasn't right. I went for a series of vigorous tests and was ultimately delivered the devastating news. I now have liver disease. How could this happen to me? I was always a healthy man. In 1983, I ran a 26-mile marathon in Erie, Pa. To be told I could not survive without a transplant was inconceivable. When I was first put on the transplant list, there were little symptoms of my disease, but the longer I remain on the list the symptoms get worse and continue to rob me of the life I once had. Living with liver disease is unpredictable. Recently, I had to have my medications changed to manage my condition. It is a struggle everyday and I pray my waiting will be over soon.

While I have been on the waiting list for a long time, I am fortunate that the medical staff here at UPMC is able to manage my illness and keep my spirits up when I am at an emotional low point. I try to fill my time as best I can by volunteering with the local organ procurement agency, the Center for Organ Recovery and Education. I also am part of a local support group in Westmoreland County that meets once a month in Greensburg. There are approximately 12 to 20 people at each meeting. In the short time I have known these patients, we have formed a bond that is unbreakable. Among this group, I am in the minority. There are more patients waiting for hearts. Several of them are in worse shape than I am. It saddens me that they are the ones who end up not getting transplanted due to the lack of organs. In fact, 25 percent of patients waiting for hearts and lungs will never get that chance. My support group has seen firsthand the effects of this, and as much as I

would love to get my liver transplant, I would gladly wait if I knew there were sicker people who needed it.

There needs to be a broader sharing of organs if people are to get a fair chance. The United Network for Organ Sharing's first and last words are "united" and "sharing." When you break those words down, there are no regional boundaries. It's time to make organs available for everyone, no matter where they live. We need to put a human face on this issue. Too many people are dying needlessly. Please do your part Senator Specter and Senator Santorum to make patients a priority in this debate.

While more work needs to be done on the legislative side, it is up to the rest of us to do our part. Many of you are well aware of the recent passing of football legend Walter Payton. If people didn't know enough about the importance of organ donation before, they do now. We need to make sure that steps are being taken to ensure people sign an organ donor card so we won't have to hear about patients dying from the lack of organs.

Some people say organ donation is a personal choice. But I am challenging Americans to look at the big picture. Imagine if you had a mother or father on dialysis for many years while waiting for a kidney transplant. Imagine if your child was born with a liver disease and needed a transplant to save his or her life. Wouldn't you start thinking differently about organ donation?

There are currently 66,000 people on the UNOS waiting list. Think about that. That's enough to fill Three Rivers Stadium. Yesterday, I spoke to some local high school students and encouraged them to become organ donors. It is my hope that they will make that personal choice. As one of 66,000 waiting for a new chance at life, I am asking that the rest of you make that choice, for it can make those of us waiting very happy.

Thank you for the opportunity to speak.

Senator SPECTER. Mr. Gilmore, you took a charter to Miami? Were your circumstances that extreme at that particular moment?

Mr. GILMORE. Yes.

Senator SPECTER. They leave almost every hour from Philadelphia's International Airport.

Mr. GILMORE. I know. Unfortunately, when I got the call, I got the call around 10 p.m. at night, and there was nothing else flying out of Philadelphia.

Senator SPECTER. So it was more the life expectancy of the liver than your life expectancy?

Mr. GILMORE. That is right. They wanted to get me into surgery at 8 a.m. the next morning, and there is always a risk if you wait and if you tarry long.

Senator SPECTER. So the liver became available at that moment, and you were notified, and off you went?

Mr. GILMORE. Yes, that is right.

Senator SPECTER. Well, I was going to ask you why you did not fly to Wichita, but now I know the answer.

Dr. Hulnick, you have commented that had the current system been in place you might have died. Can you amplify why the current system would have left you in a more precarious position than at the time you got the transplant?

Dr. HULNICK. At the time I got my transplant, fortunately for me it was almost 13 years ago, and the University of Pittsburgh was essentially the only program that was doing liver transplants.

Senator SPECTER. So they had more availability of livers to transplant because of that?

Dr. HULNICK. Yes, and if it were today the liver would have stayed around Alabama, and perhaps nothing would have become available in Western Pennsylvania, and I would not have survived. But given the circumstances and the timing, that there were just

so few liver transplant programs active at that time that they were able to more broadly share the livers.

Senator SPECTER. Mr. Somerville, you described yourself as a Status 7 person. I am sorry, Status 3 person, pardon me, and I have a chart here that explains that to some extent, but could you explain what that means, and explain the difference between 1, 2A, 2B, and 3?

Mr. SOMERVILLE. To the best of my ability. Under Status 3 I am under a doctor's care and occasionally admitted to the hospital because of conditions that my medical condition warrants, and I take regular medications and such, but I am ambulatory. I am not attached to the hospital per se.

Mr. SPECTER. Mr. Gilmore, what status were you when you had your liver transplant?

Mr. GILMORE. To my recall, I believe I was a Status 3, because I was outside of the hospital. Occasionally I would have to go back in the hospital and I would become a Status 2.

Senator SPECTER. Dr. Reyes, why do we not put Mr. Somerville on the Miami list as well?

Dr. REYES. I have actually sent patients to Miami that were——

Senator SPECTER. You have to speak up a little bit.

Dr. REYES. I have actually sent patients to Miami. We transplanted a boy 15 years ago. He subsequently became an adult and he needed a retransplant. He lived in Chicago, was listed there, double-listed in Nebraska, was triple-listed here, and actually the program in Chicago was working up his mother, his 65-year-old mother for a liver-related transplant that I thought was dangerous to the mother, and I told him go to Miami. He did, and he was transplanted 2 days ago.

Senator SPECTER. Let us come back to my question. How about Mr. Somerville for Miami?

Dr. REYES. Mr. Somerville could also go to Miami. Patients are free to double-list or triple-list.

Senator SPECTER. I am about to get you a new patient, Dr. Reyes. Mr. Somerville, why not send him to Miami? Could you practice medicine here this morning? The question is, why doesn't Mr. Somerville get sent to Miami or Wichita?

Dr. REYES. Senator, we allow all of our patients, independent of their status, to go anywhere for a second opinion, or to be double-listed. I support it. I think particularly with my patients I talk to their parents. These babies belong to their parents. They do not belong to me. I do not hold on to the patients. I do not hold on to the organs. I let them go where they feel, where they as patients feel that they can get the best care.

Mr. Somerville feels he can get his best care here at this center, and I would support that.

Senator SPECTER. Well, Mr. Somerville, I am not satisfied with that answer, so I come back to you. Have any of your doctors—and I know Dr. Reyes is not your doctor, or I have no reason to believe that he is. Have your doctors at Pittsburgh Medical Center suggested you go some place else to get a liver transplant?

Mr. SOMERVILLE. They have not, but my insurance company has, the one that I work for. I have chosen to remain here at the University of Pittsburgh Medical Center, and I think I also found out

during the 1996 hearings with HHS that there was testimony that was given that people with chronic problems such as primary sclerosing cholangitis really are above Status 3, perhaps to Status 2.

Senator SPECTER. Well, have you considered going to another center?

Mr. SOMERVILLE. That is a discussion we have had. At the present time, my situation is manageable.

Senator SPECTER. But that could change at any time?

Mr. SOMERVILLE. That could change. It is an unpredictable disease.

Senator SPECTER. Well, my thought would be, if I were in your position—and I do not want to practice medicine here this morning. I will say that I practiced a fair amount of it, however, with myself, and found it very rewarding to do that, that it is something you ought to give consideration to. It is pretty much a tough line here as to how you protect yourself, and if you can get a transplant in Miami, like Mr. Gilmore did, more power to you.

These medical decisions are really difficult. Doctors do their very, very best, but I found there is nothing like a little personalized research.

Mr. SOMERVILLE. I received wonderful medical care at this center. The doctors understand me. They know me. The transplant coordinators know my situation, and it is somewhat personalized to the effect that I feel I am perhaps getting the best medical service in the country, and that is perhaps the reason why I have not opted to go elsewhere.

Senator SPECTER. To personalize it a little bit, the day that Governor Casey had his transplant I had a resection of a brain lesion, and there was a tiny regrowth, and I got a pretty much unanimous opinion to go through another surgery, and I found with a lot of research that I had—to give a little more publicity to the University of Pittsburgh Medical Center right down the street here, I solicited about 35 different opinions—it may be a little easier for me to get through to the specialist in Seattle or Dallas than some—and finally got this gamma knife, and knock on wood, so far it is fine, but I have had a couple of other encounters where a little activism can be a very healthy thing.

Senator Santorum.

Senator SANTORUM. I do not have any questions, other than I would just like to comment that I appreciate your taking your time and efforts in testifying before this committee, and your other testimony and your work within the transplant community in support of our efforts here in the Congress. You are the reason we are doing this, and I cannot thank you enough for your energy that you have given to the cause, and I thank you.

Senator SPECTER. Thank you very much, Senator Santorum, for joining me today and for your leadership, and for your tenacity on this, as on so many other issues.

One thought which occurs to me is really the lack of publicity about this issue. Senator Santorum puts his finger on it when he puts his finger on his driver's license, and I think this would be a good subject for a movie, or, better yet, a television movie which

would portray Mr. Gilmore's life, or Mr. Somerville's life, or Dr. Hulnick's life.

Senator SANTORUM. There was a TV movie last year, or earlier this year, Nicholas.

Senator SPECTER. I see quite a few heads nodding, but only about an eighth of the audience.

Senator SANTORUM. Maybe we can get CBS to do a rerun.

Senator SPECTER. Maybe we will get Steven Spielberg to do one. We will get a lot of attention.

Dr. Reyes, did you have a comment?

Dr. REYES. Unfortunately, most of the media attention that this issue has gotten has been negative publicity.

Senator SPECTER. Why is that?

Dr. REYES. Because of the debates over the regulations. I believe, as Mr. Nathan I am sure would support, that if there is positive media coverage of organ donation and organ procurement and results with transplantation, organ donation rates will go up.

These problems, these issues in Congress, the delays, et cetera, paint this problem in a negative way with the public. I sat on the Liver and Test Committee for 6 years with the other representatives of other centers trying to find better policies. We could not do it.

Members from HHS sat with us, never said a word until 3 years before the regs came, and we were urged—we were urged to come up with a policy. We could not do it. It was only with the recommendations by the Secretary that we received guidelines and standards. That is all.

The Secretary did not come down with the gavel. She did not come down telling us that she was going to take our toys away. She came down with standards. We still had the ability to set policy, but the Secretary is setting the standards. I think if we can accept that, then we can move on with the business of developing the policy according to fairness and the standards that have been set, and then focus on organ donation. We have to do that, and that is what UNOS should be doing, focusing on the organ donation.

Senator SPECTER. Well, as Mr. Gilmore and Mr. Somerville have mentioned Walter Payton, could his life have been saved with a transplant, an early transplant?

Senator SANTORUM. He had cancer on top of it.

Senator SPECTER. Mr. Gilmore, do you want the last word?

Mr. GILMORE. Yes. I just wanted to mention very briefly that, like Mr. Somerville, I, too, am very active in trying to share information with the Philadelphia community, especially with African Americans, as far as becoming organ donors. I agree that is a key component to this issue.

But a key issue also, I believe, is the discrimination that also exists not only between Mrs. Smith, who is a Status 1 patient here, and Mr. Jones, who is a Status 3 patient in Miami and ends up getting the transplant over Mrs. Smith, but also in terms of African Americans, if you look at the economic realities with African Americans, with the majority of minorities, Hispanics, the fact is they are unable to transport back and forth like I did from Philadelphia to Miami and spend $8,000 for a jet, and be in debt $15,000 like I was.

I was fortunate to have the resources to travel, but most Americans, I would believe, and especially African Americans, cannot do that.

Senator SPECTER. When you say African Americans have to wait twice as long, is that related to their inability to take a charter jet, as you did, to find an available organ?

Mr. GILMORE. It is an economic issue. Yes, there are some biological issues involved as well, but primarily it is an economic issue.

Senator SPECTER. Is there any economic issue besides the jet to get to where the organ is? Is it the cost of the transplant?

Mr. GILMORE. That is an issue, I guess, if they do not have the best insurance. That certainly is an issue.

Senator SPECTER. But are you suggesting there is any discrimination, aside from the dollars and cents, against somebody because of minority status?

Mr. GILMORE. No, I am not suggesting that, but what I am suggesting is, when an African American—a relative of mine, for example, knows my situation and knows what I have been through, and he says, well, Cleo, that is fine for you, but I do not have $8,000 to travel to Florida, and so basically, Cleo, what you are telling me is that in order to get a transplant I have to do what you did, and I do not have those resources, he is indirectly, I guess, chronicling in his mind that there is some unfairness in the system with African Americans and with Hispanics.

As I said, fortunately I had the resources. I had a 401(k) plan. I had the resources to travel. But this is just not the case with most people, and without question—and I would encourage Mr. Somerville to do some active research. That is what I did. I believe that doing the research saved my life.

At the time I had a bilirubin level of 33. I was yellow. I had lost over 50 pounds. I was at death's door, I really was, and by the same token I was not sick enough to be in the intensive care unit. I was somewhere in between, and I am sure that there were patients who did not get a transplant because I happened to get mine before they did, because I was able to travel.

Now, on the one hand, one could say, well, Cleo, what you may end up doing, this may end up slapping you in the face one day, because who knows, I may need another transplant one day. Primary sclerosing cholangitis is an autoimmune disease, which means that it can recur.

But I am here to tell you that if that ever happened again I would like to see a system based on fairness rather than based on economics.

Senator SPECTER. Well, we are trying to do our best to extend health coverage in a variety of ways with full deductibility, and small businesses joining together, and a whole variety of approaches, but it is one which we will try to address in this area as well.

CONCLUSION OF HEARING

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 11:10 a.m., Friday, December 3, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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