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UTILIZING PUBLIC POLICY AND TECHNOLOGY TO STRENGTHEN ORGAN DONOR PROGRAMS

HEARING

BEFORE THE

SUBCOMMITTEE ON INFORMATION POLICY, CENSUS, AND NATIONAL ARCHIVES

OF THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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UTILIZING PUBLIC POLICY AND TECHNOLOGY TO STRENGTHEN ORGAN DONOR PROGRAMS

TUESDAY, SEPTEMBER 25, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INFORMATION POLICY, CENSUS, AND NATIONAL ARCHIVES,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:08 p.m. in room 2247, Rayburn House Office Building, Hon. Wm. Lacy Clay (chairman of the subcommittee) presiding.

Present: Representatives Clay, Reyes, and Turner.

Also present: Representatives Lynch, and Costa.

Staff present: Darryl Piggee, staff director/counsel; Jean Gosa, clerk; Adam C. Bordes, professional staff member; Nidia Salazar, staff assistant; Michelle Mitchell, legislative assistant, Office of William Lacy Clay; Allyson Blandford and Jay O'Callaghan, minority professional staff members; and Benjamin Chance, minority clerk.

Mr. CLAY. The Committee on Oversight and Government Reform, Subcommittee on Information Policy, Census, and National Archives will come to order.

Let me say good afternoon and welcome to today's hearing examining ongoing efforts to increase public participation in organ donor programs. Organ donation is one of modern medicine's most effective life-saving therapies. In fact, over the last 20 years more than 390,000 organ transplants have been performed successfully. Unfortunately, during that same period of time, the waiting list for an organ transplant has more than doubled. Last year in the United States over 6,000 Americans died while waiting for their lives to be renewed through transplantation.

As we convene this hearing, nearly 97,000 patients are waiting for an organ donation. This includes over 1,300 anxious men, women, and children from my District in Missouri. After personally witnessing the devastating effects of patients trapped on dialysis, I am convinced that Congress must play a vital role in elevating the issue of organ and tissue donation to become a National priority.

Yesterday I introduced H.R. 3635, the Everson Walls and Ron Springs Gift for Life Act to raise awareness and increase organ donation. This legislation will provide assistance to State organ donor

programs and track the long-term health of individuals generous enough to become organ donors.

In addition, it establishes a national organ and tissue donor registry resource center charged with providing information, technical assistance, and grants to donor registries administered by the States.

I would like to thank members of the transplant community for assisting me in crafting this legislation. Today we welcome a group of distinguished panelists from both the medical and patient communities. I look forward to their testimonies.

I also want to welcome two guests to this committee, one being Representative Jim Costa of California, who is also part of the Organ and Tissue Donor Caucus here in the House. Thank you for being here, Mr. Costa. You may make an opening statement if you care.

[The prepared statement of Hon. Wm. Lacy Clay follows:]

Opening Statement of Rep. Wm. Lacy Clay (D-MO), Chairman
Subcommittee on Information Policy, Census, and National Archives
House Committee on Oversight and Government Reform

Hearing on Organ Donation
September 25, 2007

Good afternoon and welcome to today's hearing examining ongoing efforts to increase public participation in organ donor programs.

Organ donation is one of modern medicine's most effective, life-saving therapies.

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Mr. COSTA. Thank you very much, Chairman Clay, for inviting me to participate in this afternoon's hearing. Your support and your passion for this issue is well known as an advocate on behalf of organ and tissue donation. Our collective efforts I believe will make a great difference.

I am pleased that, along with you, other of our colleagues share in joining as Members of the Congressional Organ and Tissue Donation Awareness Caucus, a new caucus, a bipartisan caucus, to advocate on behalf of organ and tissue donations, which too often, as you noted in your opening statement, is a forgotten part of the health debate.

It is great to see athletes here today like Mr. Everson Walls. We hope that he will be joined by Mr. Springs. We all know that football players—it is the season—are often idolized by their fans and revered for their athletic prowess, but Mr. Walls comes this afternoon and shares the passion with us because he is not just a holder of a Super Bowl Ring or one who mustered 57 career interceptions—I hope I got that correct.

Sadly, I believe that a number of those interceptions were against the 49ers, my home team. But, nonetheless, with great respect, Mr. Walls is a hero in every sense of the word. His friend, Ron Springs, who we hope to acknowledge, as well, was the recipient of Mr. Walls' awareness and understanding that he had the gift of life.

What we are talking about are over 100,000 people, as the chairman noted, who are on the waiting list for organ transplants. Nearly 6,000 of them pass away every year before a much-needed organ becomes available to them.

So we as Members of Congress think we have to do more through our legislative efforts, through our advocacy in creating greater awareness of this issue, and support and encourage facilitating and collaborating organ and tissue donation process.

We have a number of witnesses here who will testify in both the first and the second panel. I am pleased to see Eunice and the roundtable of support groups are an important part of this collective effort. We will hear later from Dr. Timothy Pruett and his predecessor, Dr. Sue McDiarmid, who is a long-time friend of mine who first brought my own awareness of the importance of the gift of life; that, in fact, we have so much that has been made in the way of progress in the way of medical science; and that we, as human beings, have the opportunity to expand and to extend others through that gift of life.

So, Mr. Chairman, I am looking forward to the testimony. We have over 300,000 minorities in my District. Nearly 80,000 nationwide are currently on the transplant list, yet too many of the minority donors still remain disproportionately low. I know that Mr. Walls, through your testimony and your efforts with us, you will help us expand that awareness. With the help of strong role models such as yourself, Congressman Clay, and Dr. Callender, I know that we stand to make great success and progress in our efforts.

This is truly wonderful and potentially a great effort and a noble one that we embark upon today.

Thank you very much, Mr. Chairman.

Mr. CLAY. Thank you very much, Mr. Costa, for that opening statement.

Now I would like to recognize my colleague, who happens to be chairman of the House Intelligence Committee, Mr. Silvestre Reyes.

Thank you for being here.

Mr. REYES. Thank you, Chairman Clay. Although I won't be able to stay for the hearing, because I just left one of my own, I did want to come by and thank publicly Everson Walls, or Cubby as he is known in Dallas, Cubby Walls, for really being the driving force behind the Everson Walls/Ron Springs Gift for Life Legislation. Thank you, Mr. Chairman, for forging that legislation, because it really has, I think, the ability to make a real difference in so many different communities around our country, and getting the message out, which is a very good news story that speaks volumes about not just friendship but commitment to a teammate.

We are all so very proud of Everson Walls for what he did for Ron Springs, but, more than that, I think for what he is about to do through our collective efforts for organ donors and educating potential organ donors and so many, we hope, thousands and thousands of recipients that will benefit and enjoy a new, better quality of life through this legislation.

I am proud to be here. Most of all, I am proud to know Everson Walls and the kind of character that he brings that is the springboard for this legislation.

Thank you, Mr. Chairman.

Mr. CLAY. Thank you very much, Mr. Chairman.

Now that the world and C-Span community knows that Everson Walls' nickname is Cubby, we welcome him, too.

Let me say, without objection, Members and witnesses may have 5 legislative days to submit a written statement or extraneous materials for the record.

Now, if there are no additional opening statements, the subcommittee will now receive testimony from the witnesses before us today.

Ms. Rubin is on her way, so we will start with testimony with Mr. Walls. Let me first introduce him.

Everson Walls is a retired NFL All-Pro cornerback, having played 14 seasons with the Dallas Cowboys, New York Giants, and Cleveland Browns. During his career he was a four-time Pro Bowl selection, three-time All-Pro selection, and was part of the New York Giants' 1990 Super Bowl championship team.

More importantly, in February of this year he became a kidney donor to his long-time teammate and friend, Mr. Ron Springs. Together, Mr. Walls and Mr. Springs now lead the Gift of Life Foundation in order to promote awareness, early detection, and prevention of kidney disease and its associated illnesses.

Let me thank you for being here today.

It is the policy of the committee to swear in all witnesses before they testify. I would like you to please stand and raise your right hand.

[Witness sworn.]

Mr. CLAY. Let the record reflect the witness answered in the affirmative.

Thank you.

I ask that you give us your statement. There is a 5-minute rule, and, of course, if you go over we will not flag you, Mr. Walls. [Laughter.]

You may proceed.

STATEMENT OF EVERSON WALLS, KIDNEY DONOR, FORMER PLAYER, DALLAS COWBOYS

Mr. WALLS. Thank you, Congressman Lacy Clay. I want to also thank some of your staff that have been so helpful in preparing me for this hearing, as well as from the moment that I met you—I think that was back in July of this year. They have been very helpful in helping in, if nothing else, get the word out about becoming a living organ donor. That would be Michelle Mitchell, Darryl Piggee, Adam Bordes.

Also I want to thank Congressman Silvestre Reyes and the people on his staff, Perry, Finney, I believe her name is, Brody. She was also very helpful. And Marvin Steel, who is also with Congressman Clay's staff, as well.

The day that is so famous now in my life and in many other people's lives is February 28th. That was the day that I decided that I would lay down my life for a good friend of mine named Ron Springs. You know, whenever you make a decision as strong as this one that is as impactful as this one was, then there are just so many people that you have to consider, because, after all, any time you make this type of decision you don't really make it by yourself. You are always shaped by not just the experiences that you have had in life, but also the people that you have come across.

My Mom—she is not here now, but she is back in Dallas—as well as my father, I must give some notice to them. My father is Weldon Walls. My mother is Weila Walls. They would obviously be extremely proud to be here right now but they couldn't make it. But as soon as I get back home, I am sure they are going to want to hear everything blow by blow on exactly what happened here.

And yes, Mr. Costa, I did get a lot of interceptions against the San Francisco 49ers, but, in defense of the 49ers, I got more against the Washington Redskins. [Laughter.]

Mr. COSTAS. I like to hear that.

Mr. WALLS. So if there are any Cowboy fans out there, I am sure they really appreciate maybe my presence, as well as Mr. Spring's spirit being here, as well, with us.

You know, any time you talk about making a life-changing decision, as I said, there are so many people that are involved with that. I am just a young man from Dallas, TX, from a small community called Hamilton Park. It is an all-African-American community in Dallas that has been established since 1954. We have had a lot of great men and women come out of that community. I think they would all be so proud of the fact that I am here right now speaking on this bill that you are trying to pass.

One person I would have to say, Ron Springs wants to thank anyone for what I have done for him. It is a long line of other people that he should thank. No. 1 is, obviously, my wife Shreill. Shreill is a person that is great friends with Ron's wife Adriene. They are the kind of people that they could hang together all day

in any event, whether it is a cookout, family reunion, graduation, or whatever. They can be with each other for 8 hours, and when they come home they are going to give each other a call and talk about what went on at that particular event. She loves Ron as if he was a brother, and I knew that without her support that there is no way I would be able to do this for Ron.

You look at the people that have really shaped my character in the past. You spoke of character, Congressman Clay. I would be remiss if I did not bring up the late Coach Eddie Robinson from Grambling State University. At the age of 17 I met this man, and his influence on my life was just astronomical. Obviously I was raised well by my parents, but when you start talking about raising a child, you have to go back to the old adage of it takes a village to raise a child, and Coach Robinson was aware of that. He was always a person that didn't care much about how a person played football, because he always wanted you first to emulate an American citizen in life, and if he knew that you were going to be a great American citizen in life, then he would always feel that he could make you into a good football player. Consequently, we had championship years there, but that pales in comparison to the lessons that Coach Robinson taught me going through life.

I have been associated with so many different types of coaches. Obviously, playing for 13, 14 years in the League you should be associated with some good players and good coaches. Tom Landry from the Dallas Cowboys in the 1980's was one of the most stern and disciplined and successful coaches to come through the NFL. I went off from the Cowboys to play with the New York Giants, Coach Bill Parcels, who was one of the most personable, as well as stern coaches I have ever been around. Being around such intelligent coaches such as Bill Belichick with the Cleveland Browns, as well.

Any time you associate with these type of people, then you would have to be a fool not to really learn something from them, not just for football but also in life.

My kids are also very proud of me, as well as I am very proud of them. My oldest daughter, Charis Walls, she is a graduate of Southern University. My son, Cameron Walls, is now attending Texas Southern University. These are my kids, and they are people that really, really care so much for what I did for Ron, as well.

Our families are so close that it was a really easy decision for me to make. Everyone always asks me, well, how could you lay down your life for someone who is not a family member. When you look at Ron Springs and you look at the dynamics of both of our families, it is as if we are related, because we are not only close through the careers that Ron and I had, but also through our wives, as well as our offspring. His daughter Era and my daughter Charis are best friends. His younger daughter Ashley and my son Cameron are also very good friends. So when you talk about something that I did, it is almost as if he is a family member.

The one thing that we realize about organ donation is that it affects everyone. It can positively affect anyone in the future who may have any types of problems from kidney disease on up to type II diabetes.

Ron's situation was as unique as anyone's. He is just like anyone else, except that he is as stubborn a football player that you want to meet. He is a guy that felt that, once he found out that he had chronic kidney disease, he ignored it, just as any normal person would do. He was in denial about it, just as any normal person would be. But the one thing about it was, as he started to realize how his body was being affected and afflicted by chronic kidney disease and type II diabetes, by that time it was almost too late. He had an amputation of his right foot. All of his toes on his left foot are also amputated. He was on dialysis for 3½ years.

As I talked to his transplant doctor, Dr. Dick Dickerman, Dr. Dickerman noted to me that Ron would not make it to his 5th year of dialysis. If anyone knows anything about dialysis, it is a process that is extremely invasive and literally draining to the human body. All of your blood is drained from your body, it goes through a filter, and it goes back inside your body. You are talking about a process that takes up to 4 to 5 hours a day. Well, Ron Springs was going through that for 3 days a week for 3½ years. He was on that kidney waiting list for 3½ years, as well. When it came down to his family trying to help him out, trying to give him aid, he had a niece that was willing to help, he had a nephew that also was willing to help. Those two procedures were not successful.

When you take a look at the peaks and valleys that anyone that is afflicted with chronic kidney disease and type II diabetes will go through, it is really trying not just on you physically, but it is trying on your spirit. I have to commend Ron, himself, for being so heroic in not giving up on life, because when you take a look at what could happen with anyone that goes through the peaks and valleys that Ron went through, he could have easily given up on the process. He could have easily given up on life. But because of his strong spiritual connection, he chose to hang in there. He chose to be strong, not just for himself, but also he realized that his family and friends cared so much about him.

I think that is what prompted me, among other things, to help Ron Springs. You know, it is one thing about being called a hero. You are really put up on a pedestal. But what I want people to know is you don't want to put that pedestal up too high, because we want everyone to realize that as long as you have two good kidneys, that you could qualify to become a living organ donor.

We don't want anyone out there to think that this is an unattainable feat. This is something that can be done by anyone, whether he is a football player, whether he is a Congressman. It doesn't matter. This is something that can be done by anyone.

I just want to say that I was just fortunate to be the one to do that. We have felt that we owe it not just to our families, not just to our friends, but to our community to start the foundation that we started. It is called the Ron Springs and Everson Walls Gift for Life Foundation. That foundation is going to be there to not just provide access and awareness to the problems with chronic kidney disease and type II diabetes, but our long-term goal would be to bring the care and that awareness to the people.

Obviously, it affects everyone in the country, but we want to really bring it to the under-served areas of the country and allow them to understand that, No. 1, you need to be tested frequently

for chronic kidney disease, and, No. 2, if you are a candidate to be a donor, then you should really consider doing that?

Mr. CLAY. Let me stop you there, Mr. Walls, and say thank you. We just got word that we will shortly be taking votes on the floor, but what we want to do now is try to ask you some questions and get your comments.

Mr. WALLS. Sure.

[The prepared statement of Mr. Walls follows:]

Opening Statement of Everson Walls, former professional football player and organ donor
Information Policy, Census, and National Archives Subcommittee
Oversight and Government Reform Committee

Hearing on Organ Donation
2247 Rayburn HOB - 2:00 P. M.
September 25, 2007

Congressman Clay and ranking member Turner:

I want to thank you for giving me the opportunity to testify before your committee. I am humbled and honored to present Ron Springs' and my story to you. Ron is unable to attend this hearing in person because he is still going through rehabilitation; but he is doing well and is on the road to recovery. He sends his regards. Therefore, I am here representing both of us and our newly formed foundation—the Everson Walls and Ron Springs "Gift for Life Foundation" (www.giftforlifefoundation.org).

Chairman Clay, before I get into my formal remarks, I must thank my friend Raynard Jackson (who is seated behind me and has been advising Ron & I on many issues involving our newly formed foundation).

I never, in my wildest dreams, thought you would ask me to participate in a hearing before the U.S. House of Representatives. As if that wasn't enough, for you to introduce a bill in congress named after Ron & I—man, that's some heady stuff. Even for someone who has played in and won a Super Bowl! So, I want to thank Raynard for introducing me to you and I look forward to working with you in the area of organ donation. Now, to my formal remarks.

Winston Churchill once stated, " To every man there comes a time when he is figuratively tapped on the shoulder and offered a chance to do a great and mighty thing, unique to him and fitted to his talents; what a tragedy if that moment finds him unprepared or unqualified for the moment that could be his finest hour."

I am not a hero, nor have I sought the spotlight since my retirement from the NFL in 1993. But, I received my tap on the shoulder in 1981 when I met Ron Springs. We were on opposite sides of the ball—me on defense as a cornerback and he on offense as a running back with the Dallas Cowboys.

Ron was a very unique athlete. He had size, speed, and the intelligence it took to become a leader on and off the field for the Dallas Cowboys. I was able to relate to Ron not just on the field, but off the field as well. Our friendship was strengthened by our family's bonding with each other.

After Ron and I both retired from the NFL, the relationship between our families became stronger. There was Ron's wife Adriene, his son Shawn (who is a current member of the Washington Redskins), daughters Ayra and Ashley. There was my wife Shreill, daughter Charis and my son Cameron There were good times all around-- during family vacations, cookouts, graduations, and Sunday dinners. It seemed as if life couldn't get any better.

Remember, I played in the NFL for thirteen years. I can say I have been associated with some of the most intelligent, respected, and talented individuals known in the world of sports..

I played with such great teams as the Cowboys in the 1980s and I was a member of Giants Super Bowl XXV championship team 1990. I realized how important teamwork was as a player and I have always tried to transfer that from on the field to off the field. I learned those lessons from playing for great coaches such as the great Eddie Robinson from Grambling State University, Tom Landry of the Dallas Cowboys, and Bill Parcels of the New York Giants. But I also learned much more from my fellow soldiers that fought in the trenches with me. Ron Springs was one of those fellow soldiers.

Ron had been diagnosed with diabetes years ago, but the disease became more acute with time. He had been placed on national transplant waiting list in 2004. His health was challenged by chronic kidney disease. There was failing eye sight, lack of circulation to his limbs, and ultimately kidney failure. One of the strongest athletes I have ever known began to show weaknesses that could not be imagined a few years earlier.

I, like most people, was very naïve about the symptoms of chronic kidney disease. I was fortunate that diabetes did not run in my family. Because of the many afflictions affecting my friend, I began to take a crash course on the subject of chronic kidney disease. I was very surprised at what I found out.

There are millions of Americans that are afflicted with chronic kidney disease, but minorities are affected disproportionately.

You have limited choices when you are afflicted with chronic kidney disease. One option is to start taking insulin, another option is to take dialysis. Dialysis is an extremely invasive procedure. In Ron Springs' case, it was more like a slow death. The process includes having all of your blood extracted from your body, filtered, and then inserted back into your body. It is not only invasive, but it is time consuming as well. Each session lasts 4-5 hours a day, and Ron Springs would endure d this procedure three times a week, for three and a half years. Unfortunately, during that time, Ron not only lost feeling in his legs, but his right foot and left toes were amputated. There is another option that is only for the fortunate, and that is to undergo a kidney transplant procedure. There are two types of kidney transplants. One is to receive the organ from a cadaver, the other, and more favorable procedure, is to receive the organ from a living donor.

Fortunately for Ron Springs, I volunteered to be his favorable option. After a barrage of tests, it turned out that I was a perfect match to become his living organ donor. On February 28th, Ron and I underwent a successful living organ donor transplant procedure. Because of this, Ron has no more dialysis treatments, and has a chance at a better quality of life. Although he has a long way to go, as far as rehabilitation is concerned, our lives and our families lives are much richer because of my decision to lay down my life for my fellow human being.

Finally, Congressman Clay, Ron and I established the "Gift for Life Foundation" to help us educate the public about the issue of organ donation. We want to educate the public on the need, the process, and the benefits of organ donation. There is a lot of mis-information surrounding organ donation that needs to be dealt with. Minorities, especially Blacks and Latinos, are extremely hesitant to register for organ donation. Some of it stems from religious reasons and others from some of the terrible things our government has done in the past, like the Tuskegee experiments.

N.F.L. Commissioner Roger Goodell and Dallas Cowboys owner Jerry Jones have pledged their support to us and our foundation to take our message across the country. They both have submitted letters of support to you for inclusion in the official record of this hearing. I would like to ask your continued support and personal involvement along with ranking member Congressman Michael Turner from Ohio.

We want to work closely with the Department of Health and Human Services, as well as the pharmaceutical industry to help us take our campaign nationally. Any help you can provide in meeting with these organizations would be greatly appreciated.

When I received this tap on the shoulder, what a tragedy it would have been if I was unqualified or unprepared for the moment that could be my finest hour. I thank God that I was able to give and extend the life of my dear friend, Ron Springs. Of all the success I have obtained both on and off the field, being used as a vessel of God is by far my finest hour. Thank you again for inviting me to participate in this hearing and I look forward to your questions.

Mr. CLAY. I will go out of order and recognize my colleague and friend, Jim Costa of California. You may proceed.

Mr. COSTA. Thank you very much, Mr. Chairman, again, for your collaboration and stepping up to the plate, as we say, to be one of the original co-chairs of the Organ Donor and Tissue Caucus. I think collectively we have great opportunity to do good things.

Mr. Walls, I suspect your friend and colleague, Mr. Springs, will have an opportunity to see your testimony here if he is not watching it live, and smile a great deal for the passion with which you have spoken of your friendship and your families. Certainly, that is the type of information and the role model that we have to convey to others out there, because, as we know, the list is far too long and too many die each year waiting, as your friend Mr. Springs may have if it weren't for your willingness to do your part as a friend.

But we know that as we try to deal with registry lists, as we try to pursue other efforts that are contained in this legislation that Congressman Clay has written, that I intend to support wholeheartedly, we need to figure out other ways that we can use forums, the media, the organizations, some that are reflected here today, to get that message out, and, as I noted in my testimony, especially within minority communities.

I mean, I don't know how many here in the audience, but I carry, if I can find it here, my California driver's license, and on the back of the driver's license we have the option to determine whether or not we want to be listed on registry as a potential organ donor. This morning I saw on the Today Show where a family was interviewed in which their daughter had been tragically killed a year ago, and yet she had spoken, even as a 16 year old, months earlier about wanting to be an organ donor if at some point something happened. Sadly, something did happen, but her parents spoke with great passion, as you do.

More of this effort needs to take place.

I want to ask you, because I have my own anecdotal stories, as we all do, when did you first become aware of the potential of, as we say, the gift of life, the potential that you and all of us have as an organ donor? Is it through your friendship with Ron Springs, or was there a previous awareness that came to you?

Mr. WALLS. Well, Congressman, I just have to say that diabetes, fortunately for my family, is nowhere in our history. That is what made what Ron and I went through pretty unique. I learned everything about chronic kidney disease and diabetes through my friendship with Ron and the problems that he was having.

You know, Ron is typical as any football player, got a lot of pride. You know, when it comes to having these type of life-changing problems, we try and sweep them under the rug.

Mr. COSTA. Right.

Mr. WALLS. But by listening to the conversations between my wife Shreill and his wife Adriene by listening to those conversations——

Mr. COSTA. It came home?

Mr. WALLS. It came home. The conversations would really upset my wife. I didn't really even get the original information from Ron, himself. But then, as I started to delve more into it, as I started

to think about what can I do to help my friend, that is when I started to do my research.

Mr. COSTA. You did your homework?

Mr. WALLS. I did my homework. And it was so strange that, you know, they talk about diabetes being the silent killer.

Mr. COSTA. Yes.

Mr. WALLS. Well, I was typical of that, because no one really wants to talk about it. That is our goal here today, to make sure and get that out to the public as much as possible.

Mr. COSTA. Well, Mr. Walls, we look forward to your active participation as a partner in our collective effort. I know Mr. Clay and myself and other colleagues have visited dialysis units within our Districts, both with chronic and acute dialysis. I think you very, very vividly described what I have seen when these patients come to these clinics three times a week hoping against hope that there may be a better future for themselves and their families.

This is very important work this afternoon. Mr. Clay, I look forward to continuing to work with your efforts.

Mr. CLAY. Thank you so much, Mr. Costa. Let me also thank you for your leadership on reviving our caucus. I am looking forward to working with you and the rest of our colleagues on issues like this that raise the level of awareness as far as organ donation and tissue donation are concerned. Thank you.

Mr. COSTA. Thank you.

Mr. CLAY. Mr. Walls, let me ask you. You know, we are all aware of health disparities, as Mr. Costa said, and barriers to adequate medical care facing the minority community. In your opinion, are community care providers such as community health clinics and others adequately focusing their attention on preventive measures in order to reduce the number of patients with chronic kidney disease? Do you think there is enough attention on it?

Mr. WALLS. You know, Congressman, I would have to say that the attention really needs to begin sooner than that. I think when you start talking about the food that we serve our kids in the elementary schools which leads to childhood obesity, when you start talking about the lack of interest in the nutrition of all Americans here in this country, I think to me that is at the root of what the problem is with chronic kidney disease and type II diabetes.

If you want to talk about prevention, then it really needs to start first of all in the community. It needs to start in the home, and you need to be aware of what you feed your children, what is healthy for them, and be aware of the history, not only in all Americans, but especially in minorities, and that our culture, itself, sometimes allows us to be subject to these problems stemming from childhood obesity.

Mr. CLAY. Thank you for that response.

One area of concern in the medical ethics community is the level of donor education provided to potential living donors. From your experience, did you feel as though your transplant team worked to provide you enough information about the potential risk and complications associated with organ donation?

Mr. WALLS. Well, I have to tell you, Congressman, when I first decided to do this I was involved with some Kidney Foundation programs and things of that nature, because Ron was involved with

it and I wanted to see what was going on with that. I have to say that when I first walked into a room everyone knew I was going to donate a kidney to Ron, and I felt like I was steak on a plate because everyone was looking at me like, ah, fresh kidneys. [Laughter.]

That is something that I just had to get over. That was my own stigmatism there that I was dealing with. But I will say that the process, itself, in my case was just extremely helpful. It was extremely supportive, because, as a donor, the medical community, the team that I dealt with, they wanted to make sure that the donor is the one that is pampered. That is the one that is really the important piece of this puzzle. The recipient, himself, of course they want him to receive a healthy kidney, but they want to make sure that the donor is perfectly comfortable with the process, because any time you talk about laying your life down for someone, having major surgery, they don't want any apprehensions from the potential donor, himself. That is the way they made me feel, and I was very happy about that, and that is what made me feel comfortable about going through with the entire process.

Mr. CLAY. Now when we initially met and you shared with me the fact that Ron Springs had no idea that you were going to donate your kidney to him, just how did you break the news to Mr. Springs?

Mr. WALLS. Well, that is a crazy story because I didn't break the news to him. I don't know if you are aware, but Ron's son, Shawn Springs, plays here in Washington for the Redskins.

Mr. CLAY. Yes.

Mr. WALLS. He wears my number 24 because I am his godfather.

Mr. CLAY. You don't hold that against him that he plays for the Redskins, do you?

Mr. WALLS. I don't hold it against him. It doesn't help him catch interceptions any, but it does help his reputation. [Laughter.]

I will say that, you know, when you talk about a guy like Ron Springs, Ron is a guy that has been a very vocal person. He was always the lawyer of the locker room. Some would say he has a big mouth. Well, his son has a big mouth, as well. His son did a story in the Washington Post while I was trying to keep this whole thing under wraps, and as he was being interviewed about his father's health, because it was known that his father was in declining health, then he let it slip that Everson is considering becoming an organ donor to his father. Once that got out not only in the Washington Post, in the days of the Internet, in less than 30 minutes it was on the cover of ESPN.com. So Ron found out through the media that this was going to be done, and of course when he called me he was so excited about it. I said yes, Ron, after taking the information that you gave me I didn't tell you that I was a complete match. Of course, Ron says, "Well, hell, let's get this done." [Laughter.]

I said, "When do you want to get it done?" He said, "Let's do it tomorrow." I said, "Ron, I need some time to tie down my family affairs. I have to have major surgery here." But after a little bit of negotiating and brow-beating on his part, we decided to not just come up with a date, but in our case, because of us being high-profile citizens, being former athletes in the city of Dallas, we had to

give a false date, because if we didn't then the hospital would have been inundated with phone calls about when is this surgery going to happen, and you really can't have that when it comes to transplant surgery.

What we did was gave a false date in March, and then we actually surprised everyone and came up with the surgery at the end of February on the 28th and it worked out well for everyone.

Mr. CLAY. And I am so glad it did.

You were required to go through both a physical and mental screening process to ensure you were a suitable candidate for donating a kidney. I guess that was after you made up your mind that you were going to go through with this. What kind of experience was that? I mean, did they adequately prepare you mentally for, I guess, the pitfalls if anything went wrong?

Mr. WALLS. You know, one thing that concerned me then and still concerns me now, obviously, you know, when you give your kidney or any type of organ you are never sure exactly how long it is going to last. I have heard some stories out there from others who have received organ donations, and, of course, there is a time life to these parts. The kidney may last 20 years for Ron. It may only last 5 years for Mr. Springs. Those were always my concerns, No. 1.

No. 2 is I was always in shape physically. I try to stay in shape. I jog. I work out a lot, swim, and do whatever I can do to try and stay physically fit, so I had no problems with the barrage of tests that came my way. They have a test called glowfill, where you actually have to swallow iodine and get shot up with a glowfill substance that is allowed to test. It allows your specimen to illuminate and they are able to better see exactly what is inside of you and just how healthy your kidneys are. It is a very invasive procedure that you just don't want to step into lightly. I had to take a CAT scan, itself, where they shoot you up with another substance that goes through your body, and it feels almost like mint going from your arm to the top of your head and it is very uncomfortable, and that was for the CAT scan, itself.

Where Mr. Springs was afraid I might have a problem was on the mental exam. [Laughter.]

There was a 500-question mental evaluation that he wasn't sure I was going to pass. Thank God I passed through that with flying colors.

So in the midst of the little humor that we had while these tests were going on, it was still a process that I just will not forget.

Mr. CLAY. Physically and mentally, how is Mr. Ron Springs doing?

Mr. WALLS. Mr. Springs mentally has always had all his faculties. He has never changed his spirit and his approach to life. He was always the clown of the party, the guy that you just love to be around. That has always been there.

Physically, after Ron received the kidney—and this is the amazing thing about it—immediately after the surgery, I mean the day after surgery, his eyes were more clear, his vision was better, his face, although ashen at the time before surgery, all of the sudden his color came to life. It was like if you didn't see him from the waist down, you would not know that Ron had any problems or

side effects from his chronic kidney disease and type II diabetes. That is one thing that gives me joy as a donor is to see him, see how he looks. Every day that I see him is a good feeling for me that I feel that, if nothing else, I did all I could for my friend and he is much better off because of it.

Mr. CLAY. And you and your friend have started a new foundation. Tell me what you expect to accomplish with the Everson Walls, Ron Springs Gift for Life Foundation.

Mr. WALLS. Well, what we intend to do with this foundation is, first of all, make sure that no one has to go through what Ron Springs went through. Give them a support base, give them awareness of how you can be affected by chronic kidney disease and type II diabetes, and also, for those that have a trust factor when it comes to going to the doctors and getting tested, to make sure that we go into those under-served neighborhoods and give them their own test.

We want to also bring in former NFL players, as well, and get the support from not only the NFL players but from the NFL and the NFL Players Association and give them a helping hand in bringing some of our fallen soldiers, so to speak, who are really ailing out there and have too much pride, really, to come to the doctor and be tested to see what kind of shape their kidneys are in.

So along with helping out the retired players and all of those in the under-served communities, we want to make sure that the awareness is there for the entire community so they can realize that, before it is too late, they need to come in and get tested, because we don't want anyone to have to go through the dialysis process that Mr. Springs went through.

Mr. CLAY. I thank you for that. You can be assured that the Congressional Donor Caucus will be a partner with your and Mr. Springs' efforts.

We also thank you for your testimony today. I believe that, Mr. Walls, you exemplify a new meaning of friend by what you did, that act of courage that you demonstrated by giving a piece of you to Mr. Springs in order to give him life. I am grateful for it. I am grateful that you brought this to the attention of this Nation because you are so high profile, and I certainly appreciate your being here today. Thank you.

Let me say that this will conclude the testimony for panel one. Again, we thank you, Mr. Walls, for your testimony. You may be excused.

At this time the subcommittee will recess and reconvene after the votes. I think it will be within about a half hour to 40 minutes.

Thank you so very much.

[Recess.]

Mr. CLAY. The subcommittee will reconvene.

We will now take the second panel.

It is the policy of the subcommittee to swear in all witnesses. May I ask you all to rise and raise your right hands.

[Witnesses sworn.]

Mr. CLAY. Let the record show that each has answered in the affirmative.

We will begin the testimony of the second panel, but before we do that I would like to invite my friend and colleague from Massachusetts, Mr. Lynch, to make an opening statement.

Mr. Lynch.

Mr. LYNCH. Thank you, Mr. Chairman. I appreciate your good work on this matter. It is no secret that the whole organ donation profession and effort has benefited my family. My brother-in-law is a live liver donor recipient, and he is doing quite well after a very serious operation back 6 years ago. He is doing great. You wouldn't know that he went through that, raising three young children with my sister, and he is doing fine.

But I am aware of the pressures and anxieties that affect families who are in this position. I have become very familiar with the whole process and the waiting list and the pain and suffering that a lot of families go through who have family members who do not get a transplant in time and those who are currently waiting.

So I think that there is a gap between what legislatively we can do to help and what science allows us to do. I believe that there is an education process that needs to go forward in this country. I think we have to redouble our efforts to help those families that are in need of transplants. I think that we can do much to expedite this process through our laws and regulations, and I think that the American people deserve better than what we are giving them right now, given the miracles of science that are allowing these donations to occur.

The technology, the medicines, the anti-rejection medicines that are now available that make this all possible are going forward in leaps and bounds, and I don't think that our legislation and our regulatory framework allows us to reap the fullest benefit of the wonderful science that is being done in this country and around the world. I am well aware that some of the greatest gains in the early years of live organ donation came from overseas, and so we can benefit from those efforts and we can help them along, as well.

But the bottom line, Mr. Chairman, I am just very happy that you are focusing on this. I know there are thousands and thousands and thousands of families that wish for your success in marshalling our efforts in this regard and strengthening our organ donor program.

With that, I yield back.

Mr. CLAY. Thank you so much, Mr. Lynch.

Let me also say I am thankful for you coming forward today and being a part of this hearing, as well as the other two Members who are not members of this committee but came forward because of their keen interest in this issue of organ and tissue donation. I appreciate your being here today.

Mr. LYNCH. Thank you, Mr. Chairman.

Mr. CLAY. On our second panel we have a distinguished group of individuals who are highly qualified to address issues associated with organ donation from a variety of important perspectives, and also included on this second panel is a witness that was supposed to be part of the first panel, but let me welcome Ms. Elizabeth Rubin.

Thank you for being here. I understand you had a little difficulty, but we are glad you made it anyway.

She is a former president and current board member of the Transplant Recipients International Organization [TRIO]. Ms. Rubin was diagnosed with liver disease nearly 15 years ago following the birth of her second child, but was fortunate enough to receive a liver transplant at the University of Pittsburgh Medical Center soon after. Since then, Ms. Rubin has dedicated her time and energy to volunteering for several non-profits involving her two passions, music and organ donor awareness. What a mixture.

Through her work with TRIO, she has become a highly distinguished public representative in the areas of donor awareness, education, support, and advocacy. In addition to TRIO, she also serves on the Speaker's Bureau of her local organ procurement organization and serves as president of a community music school in Media, PA.

Ms. Rubin resides in the greater Philadelphia area with her husband, Bruce, and their two daughters, Isabel and Beatrice.

Thank you for being here.

Also we have Dr. James Burdick, who serves as Director of the Division of Transplantation at the Health Resources and Services Administration of HHS. Prior to his appointment, Dr. Burdick was a professor of surgery at Johns Hopkins School of Medicine, as well as a past president of the United Network for Organ Sharing [UNOS].

Thank you for being here, Doctor.

We also have Dr. Timothy L. Pruett, who is director of Transplantation at the University of Virginia Health System in Charlottesville and also serves as president of the Organ Procurement and Transplantation Network and the United Network for Organ Sharing. He previously chaired the open UNOS Membership and Professional Standards Committee as well as its Policy Compliance Subcommittee, and also served on its Ethics and Pediatric Transplantation Committees.

We appreciate your time here today.

Ms. Sue Dunn is the president-elect of the Association of Organ Procurement Organizations, as well as president and CEO of Donor Alliance, a federally designated organ procurement organization based in Denver, CO. Ms. Dunn serves on a variety of United Network for Organ Sharing committees, and continues to represent the donation community through her participation with the Association of Organ Procurement Organizations and the Donor Awareness Council.

We are so glad to see you today.

Dr. Clive O. Callender is the founder of the National Minority Organ Tissue Transplant Education Program [MOTTEP], which is dedicated to increasing minority donation rates nationally. MOTTEP is the first national organization to identify a twofold solution to the No. 1 problem in transplantation, the shortage of donors. The solution includes decreasing the number of persons being added to the national waiting list through a health promotion disease prevention campaign, while simultaneously increasing the number of minority donors.

Dr. Callender serves as the chairman of the Department of Surgery at the Howard University Hospital and as a professor at the

Howard University College of Medicine. He is a graduate of BW Hunter College and Mahari Medical College.

Welcome, Doctor. I am so glad to get the opportunity to meet you.

Dr. Jeffrey Crippin is the medical director of the Liver Transplant Program at Barnes Jewish Hospital and a professor of Medicine at the Washington University School of Medicine in St. Louis, which both facilities I represent proudly. He is a graduate of the University of Notre Dame and the University of Kansas School of Medicine and is the immediate past president of the American Society of Transplantation.

I want to welcome you all to today's hearing.

I will just ask each witness to be aware that you will have a 5-minute clock. Would you please try to observe it in your opening statements.

We will start here with Dr. Burdick. You may proceed.

STATEMENTS OF JAMES BURDICK, M.D., DIRECTOR, DIVISION OF TRANSPLANTATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; TIMOTHY PRUETT, M.D., PRESIDENT, UNITED NETWORK FOR ORGAN SHARING; SUSAN DUNN, PRESIDENT-ELECT, ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS; CLIVE O. CALLENDER, M.D., FOUNDER, MINORITY ORGAN TISSUE TRANSPLANT EDUCATION PROGRAM; JEFFREY S. CRIPPIN, M.D., PAST PRESIDENT, AMERICAN SOCIETY OF TRANSPLANTATION; AND ELIZABETH M.P. RUBIN

STATEMENT OF JAMES BURDICK, M.D.

Dr. BURDICK. Thank you very much. Good afternoon, Chairman Clay, Mr. Lynch. Thank you for the opportunity to meet with you today on behalf of the Health Resources and Services Administration [HRSA], to discuss the roles and responsibilities of the Division of Transplantation in strengthening our Nation's organ donor programs and awareness activities.

I appreciate your continuing support of the organ donation and transplantation programs and your organization of this very heartwarming and wonderful hearing.

The need for organ transplants continues to grow, and this demand continues to outpace the supply of transplantable organs. Nineteen people in this country will die every day because a life-saving organ does not become available to them. During the past decade, the number of deceased donors increased between 2 to 3 percent annually, while the annual growth rate in the number of individuals waiting for an organ transplant increased by approximately 8 percent. Even with the recent unprecedented 10.8 percent increase in the number of deceased donors in 2004, followed by a 6.2 percent increase in 2005 related to the Donation Breakthrough Collaboratives, there still were about 97,000 individuals waiting for an organ transplant at the end of 2006, as you recognized, Chairman Clay, in your initial remarks.

HRSA is responsible for administering a number of organ donation and transplantation programs. The National Organ Transplant Act [NOTA], Public Law 98–507, as amended, authorized the cre-

ation and operation of the Organ Procurement Transplant Network, the operation of the Scientific Registry of Transplant Recipients, and grants and contracts to conduct projects designed to increase the number of organ donations.

Additional program authorities were provided by the Organ Donation and Recovery Improvement Act [ODRIA], some called the Frist bill, Public Law 108–216, which amended NOTA to help increase the number of organ donors and number of organs made available for transplantation.

The key additional authorities under ODRIA include grants to States to support organ donation awareness; grants and contracts to support public education and outreach activities designed to increase the number of organ donors, including living donors; grants to qualified organ procurement organizations and hospitals to establish programs to increase the rate of organ donation; the expansion of grantmaking authority, to include public institutions; the development and dissemination of educational materials to inform health care professionals and other appropriate professionals about organ, tissue, and eye donation; financial assistance to living donors to help defray travel and other incidental, non-medical expenses; and mechanisms to evaluate the long-term effects of living organ donation.

In 2006 a total of 28,923 organ transplant operations were performed nationwide, and that was up from 28,112 the year before, a little under 2,000 [sic] more. From these operations in the year 2006, 31,184 organs were transplanted. Of that number, about 78 percent were deceased donors, 22 percent living donors.

At HRSA, one of the ways we are keeping donation efforts on the fast track is through our highly successful Organ Donation Breakthrough Collaborative. The Collaborative brings together donation professionals and hospital leaders to identify and share best practices to maximize organ donation in their facilities. The goal is to raise the number to 75 percent of eligible donors actually becoming donors. The results are most impressive. Since 2003, the number of hospitals that have achieved the 75 percent goal has increased from 55 to 301. The national average of donation has risen by 10 percent across the board, and we have over 20 percent more actual transplants.

This year HHS joined with private companies and organizations across America in encouraging their employees to Give Five, Save Lives. The Give Five, Save Lives challenge asked employees to support donation by taking 5 minutes out of their work day to enroll in a State organ donor registry or sign a donor card.

In February, HRSA announced the results of a 2005 Gallup Organization survey which indicates that Americans continue to strongly support the donation of organs and tissues for transplantation. More important, the survey also found that 52 percent of Americans have taken personal actions to become organ donors, up from about 28 percent in a similar survey done in 1993.

Despite these advances, HRSA is humbled by the fact that people are still dying because of the lack of available organs. In our vigilance, HRSA sustains support for other donation programs. The OPTN, which HRSA manages, continues to improve the efficiency of the organ transplantation system by improving organ allocation

policies and monitoring policy compliance by transplant programs and OPOs. Grants were awarded to OPOs and hospitals to establish programs coordinating organ donation activities.

In our outreach efforts, HRSA maintains support for public and professional education programs. Working together, we are making great strides, but we still have a long way to go.

We recently celebrated 50 years since the first successful organ transplant, which was done in Massachusetts, and we have come a long way; however, while nearly 29,000 individuals received life-saving transplants in 2006, the need to increase the number of successful transplants remains critical.

There are close to 97,000 patients on the national waiting list, and 19 will die every day because a life-saving organ does not become available to them. Working together, we can change these numbers. HRSA is proud of its leadership role in this most worthwhile effort, and there are clear signs we are moving in the right direction, but we must do everything we can to keep the momentum going.

So, finally, thank you. Thank you for giving me the opportunity to come here today on behalf of all of those waiting for a transplant to discuss the organ donation and transplantation and for your dedication and interest to these vital programs.

Eventually I would be happy to answer any questions.

[The prepared statement of Dr. Burdick follows:]

Testimony
Before the Committee on Oversight and Government Reform
Subcommittee on Information Policy, Census and National Archives
U.S. House of Representatives

Organ Donation: Utilizing Public Policy and Technology to Strengthen Organ Donor Programs

Statement of
James Burdick, M.D.
Director, Division of Transplantation
Healthcare Systems Bureau
Health Resources and Services Administration
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00 pm
Tuesday, September 25, 2007

Good afternoon Mr. Chairman, Members of the Subcommittee. Thank you for the opportunity to meet with you today on behalf of the Health Resources and Services Administration (HRSA) to discuss the roles and responsibilities of the Division of Transplantation in strengthening our nation's organ donor programs and awareness activities. I appreciate your continuing support of the organ donation and transplantation programs.

Background

The need for organ transplants continues to grow and this demand continues to outpace the supply of transplantable organs. Nineteen people in this country will die every day because a life-saving organ does not become available to them.

During the past decade, the number of deceased donors increased between 2-3 percent annually while the annual growth rate in the number of individuals waiting for an organ transplant increased by approximately 8 percent. Even with the recent unprecedented 10.8 percent increase in the number of deceased donors in 2004, followed by a 6.2 percent increase in 2005, there were still about 97,000 individuals waiting for an organ transplant at the end of 2006.

HRSA is responsible for administering a number of organ donation and transplantation programs. The National Organ Transplant Act (NOTA) (P.L. 98-507), as amended, authorized the creation and operation of: (1) the Organ Procurement and Transplantation Network (OPTN), operated under contract with HRSA, which facilitates the matching of donor organs with individuals waiting for an organ transplant; (2) the operation of the Scientific Registry of Transplant Recipients (SRTR), which facilitates

the ongoing evaluation of the scientific and clinical status of organ transplantation; and (3) grants and contracts to conduct projects designed to increase the number of organ donors.

Additional program authorities were provided by the Organ Donation and Recovery Improvement Act (ODRIA) (P.L. 108-216), which amended NOTA, to help increase the number of organ donors and number of organs made available for transplantation. The key additional authorities under ODRIA include: (1) grants to States to support organ donation awareness programs; (2) grants and contracts to support public education and outreach activities designed to increase the number of organ donors, including living donors; (3) grants to qualified organ procurement organizations and hospitals to establish programs to increase the rate of organ donation; (4) the expansion of grant making authority to include public institutions; (5) the development and dissemination of educational materials to inform health care professionals and other appropriate professionals about organ, tissue and eye donation; (6) financial assistance to living donors to help defray travel and other incidental non-medical expenses; and (7) mechanisms to evaluate the long-term effects of living organ donation.

Current Activities

In 2006, a total of 28,923 organ transplant operations were performed nationwide, up from 28,112 the year before. From the 2006 operations, 31,184 organs were transplanted; of that number, 24,461 organs came from deceased donors (78.4 percent), and 6,723 transplanted organs were from living donors (21.6 percent).

At HRSA, one of the ways we are keeping donation efforts on a fast track is through our highly successful Organ Donation Breakthrough Collaborative. The Collaborative brings together donation professionals and hospital leaders to identify and share best practices to maximize organ donation rates in their facilities. Some of the Collaborative outcomes include: Hospital-Organ Procurement Organization (OPO) teambuilding, increased donors after cardiac death, and increased conversion rates and donors in non-Collaborative hospitals. The goal is to raise donation rates to 75 percent of eligible organ donors. The results are most impressive: since 2003, the number of hospitals that have achieved the 75 percent goal has increased from 55 to 301.

To complement the Organ Donation Breakthrough Collaborative, the Organ Transplantation Breakthrough Collaborative was initiated in October 2005. This Collaborative is designed to make more organs available for transplantation by increasing the average number of organs retrieved from each donor. The goal of this Collaborative is to increase the number of organs transplanted from deceased donors by 22.6 percent.

This year, HHS joined with private companies and organizations across America in encouraging their employees to "Give Five-Save Lives." The "Give Five-Save Lives" challenge asked employees to support donation by taking five minutes out of their workday to enroll in a State organ donor registry or sign a donor card.

"Give Five-Save Lives" grew out of our Workplace Partnership for Life program, which today includes more than 11,000 workplace partners committed to addressing the shortage of transplantable organs. Through this Workplace Initiative, more than 400,000 individuals signified their intent to be organ donors in State registries over the 2006 holiday season from Thanksgiving to the New Year.

In February, HRSA announced the results of a 2005 Gallup Organization survey which indicates that Americans continue to strongly support the donation of organs and tissues for transplantation. More important, the survey also found that 52.3 percent of Americans have taken personal actions to become organ donors since a similar 1993 survey on donation.

Donor families want things to proceed the best way possible to have some good come out of tragedy. Consistent with our efforts to increase organ donation, there are strong safeguards in place to ensure that life-saving care of the critically ill patient comes first. There is a strict prohibition against the transplant team participating in the care of the patient who is a potential donor. There is also a thorough consent process which includes time for the family to think about and discuss the decision, and donation can only proceed with a signed consent. Three IOM reports have supported the value of donation after cardiac death, when appropriate.

Last month, HRSA announced grant winners under the State Donor Registry Support Program. The grants help States without a registry to develop one, and help those States with a registry to make enhancements to keep pace with technology and new information. The aim of the program is to help ensure that all U.S. residents have an opportunity to indicate and store their donation wishes where they can be reliably retrieved at their time of death.

HRSA currently operates two demonstration grant programs designed to increase knowledge about practices that are effective in increasing the number of organs available for transplantation. The Social and Behavioral Interventions to Increase Organ and Tissue Donation grant program funds projects to implement and evaluate social and

behavioral studies to increase family consent to donation and/or individual intent to donate. The Clinical Interventions to Increase Organ Procurement grant program focuses on clinical activities that begin after consent is determined or given at time of death and extend until transplantation. Improving these clinical activities influence whether a particular donor actually progresses to become a donor and the number and quality of organs that may be procured for transplantation.

HRSA also awarded a cooperative agreement to the Regents of the University of Michigan with a subcontract to the American Society of Transplant Surgeons to provide support for reimbursement of travel and subsistence expenses incurred toward living organ donation with priority given to those potential donors without the financial means to pay these expenses.

Three hundred twenty-three hospitals have recently won the Department's Medal of Honor for substantially raising the organ donation rates of eligible donors from their facilities. The ceremony to congratulate these hospitals will be held this October in Tennessee.

Despite these advances, HRSA is humbled by the fact that people are still dying because of the lack of available organs. In our vigilance, HRSA sustains support for other organ donation programs. The OPTN, which HRSA manages, continues to improve the efficiency of the organ transplantation system by improving organ allocation policies and monitoring policy compliance by transplant programs and OPOs. Grants were awarded to OPOs and hospitals to establish program coordinating organ donation activities. In our outreach efforts, HRSA maintains support for public and professional education programs.

HRSA is pleased that, in response to a Departmental request, the Department of Justice's Office of the Legal Counsel (OLC) issued an opinion on March 28, 2007 concerning the proper interpretation of the criminal prohibition on organ transfers for "valuable consideration" in section 301 of NOTA. The OLC concluded that paired exchanges and living donor/deceased donor exchanges do not involve "valuable consideration" under section 301 and are therefore not prohibited under this statute. The published opinion is binding on U.S. Attorneys' offices (which have the primary role in enforcing Federal criminal laws, such as section 301). Because of this opinion, concerns about the legality of paired exchanges or of living donor/deceased donor exchanges have been resolved, enabling the OPTN contractor to operate a nationwide paired exchange system. We believe that this will result in hundreds of additional lives saved each year.

Working together, we are making great strides, but we still have a long way to go.

Future Activities

HRSA is always looking for new and better ways to increase the number of organ donors and donor awareness. Some major activities underway include:

Breakthrough Collaboratives

Both the Organ Donation Breakthrough Collaborative and the Organ Transplantation Breakthrough Collaborative are designed to rapidly spread best practices of organ procurement organizations and donor hospitals to increase the number of deceased donors and to increase the number of organs made available for transplantation from each deceased donor. We will continue these efforts.

Our most recent initiative is the Transplant Growth and Management Collaborative. The goal of this collaborative is to save or enhance thousands of lives a year by maximizing the number of organs transplanted from each and every donor and building the necessary capacity within the Nation's transplant programs to transplant 35,000 organs annually. Elements of the Initiative include: a best practices study (December 2006 – February 2007), expert panel meeting (May 2007) and a Transplant Center Growth and Management Collaborative (to be launched in October 2007).

Organ Procurement and Transplantation Network (OPTN)

The OPTN is working to revise the national kidney/kidney-pancreas allocation policy to optimize net lifetime survival benefit of kidney/kidney-pancreas transplantation. Additionally, the OPTN is working to improve the information technology and operations infrastructure of the OPTN to allow more rapid and efficient placement of deceased donor organs.

Scientific Registry of Transplant Recipients (SRTR)

The SRTR conducts analyses of information for all organ donors and transplant recipients to be used for public and professional information and policy making purposes.

Organ Donation Support

The program will continue to test new approaches to increase the number of donors as well as the number and quality of donor organs for transplantation. We are looking for approaches that yield results.

Public and Professional Education Programs

The programs will continue to promote organ and tissue donation through a variety of initiatives targeted to the general public and to medical and other professionals who are influential in the organ donation process. We must continue to get the word out.

Conclusion

While nearly 29,000 individuals received life-saving transplants in 2006, the need to increase the number of successful transplants remains critical. There are close to 97,000 patients on the national waiting list to receive an organ, and 19 will die every day because a life-saving organ does not become available to them.

Working together, we can change these numbers. HRSA is proud of its leadership role in this most worthwhile effort. There are clear signs we are moving in the right direction, but we must do everything we can to keep the momentum going.

Thank you for giving me the opportunity to come here today to discuss the organ donation and transplantation, and for your dedication and interest in these vital programs. I would be happy to answer any questions you have.

Mr. CLAY. Thank you so much, Doctor.

Dr. Pruett, you may proceed.

STATEMENT OF TIMOTHY PRUETT, M.D.

Dr. PRUETT. Mr. Chairman, Mr. Lynch, I appreciate the opportunity to come and speak to you today. I would also like to applaud the Congressional Organ Donor and Tissue Caucus for what it has done and what it will do in the future, and would also like to applaud you for the Everson Walls and Ron Springs Organ Donation Support Act of 2007. It speaks legions to what we can do for our citizens.

My name is Timothy Pruett. I am the Strickler Family Professor of Transplantation and Surgery at the University of Virginia and the current president of the Organ Procurement and Transplantation Network and the United Network for Organ Sharing. For all that mouthful, the UNOS is a non-profit organization which operates the OPTM contract with HRSA, but it is not my intent today to speak as an official representative of the transplant community; rather, I would like to speak for the patients and families that I have seen as an individual providing transplant care for the past 20 years.

For the most part, people of all ages with end-stage kidney, liver, heart, and lung problems will live longer and better with an organ transplant than with other forms of medical support. Unfortunately, the numbers of people waiting for the organs greatly outstrips organ availability from deceased individuals, and because of increased waiting time the continuing gap between the numbers of people waiting and organs available, the number of Americans like Mr. Walls earlier described today step forward every year to donate an organ to another person. And although many types of organs can be transplanted with live organs, this amazing act of generosity is most frequent with those that need and receive kidney transplants.

From a systems perspective, a kidney from a live donor is best. It lasts longer in the recipient. It is an easier operation to plan for the recipient and the medical center. It functions more quickly and reliably than one from a deceased donor. In short, if you needed a kidney, you would want to receive one from someone that is alive and not dead.

The first kidney transplant that was performed came from a live donor, as Dr. Burdick said. In 2006 over 30 percent of the kidneys transplanted in the United States came from live organ donors. It is a form of organ donation that our people have embraced for more than 50 years.

The executive and legislative branches of the Government have recently weighed in regarding the value of live organ donation. Because there are so many instances where Americans are willing to donate but biology gets in the way, a variety of pair donation have been proposed to increase in this type of donation.

Congress has recently addressed the issue through legislation, is on the verge of passing H.R. 710, the bill named for former Representative Charlie Norwood. That bill officially provides what the Department of Justice has recently approved in memo form, that pair donation between live donors and recipients does not con-

stitute valuable consideration, is therefore legal under Section 301 of NOTA.

In 2006 a directive was published in the Federal Register instructing the OPM to develop policies regarding living organ donors, living organ recipients, including policies for equitable allocation of living donor organs, in accordance with section 121.8 of the final rule.

It is clear that the value of living organ donation and transplantation is an activity to be encouraged from the perspective of those who need to receive organs, the medical community, those that reimburse organ transplantation, and the Government and oversight community.

The live donor does an extraordinary act, lying down on an operating room table, giving a piece of himself or herself for another person, placing one's health and safety in the hands of doctors and nurses when there is no direct medical benefit for that person. Our society and Treasury gets a great deal of benefit from this form of generosity. Unfortunately, the pain of recovery from the procedure of removing a kidney or any other organ is often not the only kind of pain that the donor suffers. Financial pain is also very common.

Significant financial disincentive to be an organ donor exists in the United States. This comes in many forms: lost wages of the donor and the family support members, temporary change in the ability to perform one's job during the recovery period, travel costs incurred during the evaluation to be a donor, potential ability to obtain and collect insurance benefits as a consequence of the donation process.

Parenthetically, Mr. Walls asked me to speak on this because he had difficulty obtaining life insurance after he was a donor for several months prior to convincing them that he would be able to live a long life.

We have no safety net for those who want to donate organs. Unfortunately, the kidney donation is relatively safe, with a very low risk of death or minimal long-term morbidity, but there are multiple reports in the transplant and lay literature, and even more personal anecdotes of significant financial hardship associated with the live organ process which have been communicated to us. This is particularly true for those individuals with personal incomes at the lower end of our financial earnings spectrum.

Although the costs of the medical workup are covered by the recipient's payer, for the person without means the personal savings, family, or employee's ability to help defray the additional expenses just do not exist.

As a society, we gain much in the quality of life from recipients and financial benefits of the acts of generosity that occur daily through organ donation.

I recently gave a talk entitled, The Ethical Aspects of Live Organ Donation, and during the discussion at this international meeting there was unanimous agreement that live organ donation was not cost neutral for any donor in any country. Not only did the donation cost the organ, or the part thereof, but it usually costs sums of moneys in lost wages and out-of-pocket expenses.

In this forum, the international community felt that we should be able to do better. In fact, if we can create a model that mini-

mizes the personal cost to the live organ donor and its family, we are likely to see more donors from people at the lower end of the financial spectrum step forward to donate for the benefit of their loved ones.

An important point of the goal is that the projected cost of making organ donation cost neutral would not be more than the savings to the system, as it costs more to keep someone on dialysis than to transplant them.

The major areas to be addressed should include health insurance, automatic Medicare eligible or some such variant in the event that the organ donor develops a medical condition requiring treatment, short-term disability and life insurance for those people who are either unable to return to work or have significant catastrophic events, reimbursement for out-of-pocket expenses, and a variety of methods are available to accomplish this means.

Mr. CLAY. Doctor, may I ask you to summarize, please?

Dr. PRUETT. Yes.

The financial benefits of our society are real, and we need to continue to develop new methods and systems that increase the numbers of organs from deceased donors. Simply to look at the live organ donation system, we penalize the patient who wants to donate an organ. We can do better.

Thank you.

[The prepared statement of Dr. Pruett follows:]

Information Policy, Census, and National Archives Subcommittee
Oversight and Government Reform Committee

"Utilizing Public Policy and Technology to Strengthen Organ Donor Programs"

Tuesday, September 25, 2007
2247 Rayburn HOB
2:00 p.m.

Statement of Timothy L. Pruett, M.D.

Strickler Family Professor of Transplantation and Surgery
University of Virginia
and
President
Organ Procurement and Transplantation Network/United Network for Organ Sharing.

My name is Timothy Pruett. I am the Strickler Family Professor of Transplantation and Surgery at the University of Virginia and the current President of the Organ Procurement and Transplantation Network/United Network for Organ Sharing. UNOS is the nonprofit organization which operates the OPTN by contract with HRSA. It is not my intent to speak as an official representative of the transplant community, but rather for the patients and families that I have seen as an individual providing transplantation care for over 20 years.

For the most part, people of all ages with end stage kidney, liver, heart and lung problems live longer and better with an organ transplant than with other forms of medical support. Unfortunately, the numbers of people waiting for organs greatly outstrips the organ availability from deceased individuals. Because of an increasing wait time and the continuing gap between the numbers of people waiting and organs available, a number of Americans step forward each year to donate an organ to another person. Although many types of organs can be transplanted with live organs, this act of amazing generosity is most frequent for those that need and receive kidney transplants. From a system operations perspective, a kidney from a live donor is best: it lasts longer in the recipient, it is an easier operation to plan for the recipient and the medical center and it functions more quickly and reliably than one from a deceased donor. In short, if you needed a kidney, you would want to receive one from someone that was alive and not dead.

The first kidney transplant ever performed came from a live donor. In 2006, over 30% of the kidneys transplanted in the US came from live organ donors. It is a form of organ donation that our people have embraced for 60 years. The executive and legislative branches of the government have recently weighed in regarding the value of live organ donation. Because there are many instances where Americans are willing to donate, but biology gets in the way, a variety of methods of "paired donation" have been proposed to increase this type of organ transplantation. Congress has recently addressed the issue through legislation and is on the verge of passing H.R. 710, the bill named for former Representative Charlie Norwood. That bill officially provides what the Department of Justice has recently approved in memo form: that paired donation between live donors and recipients does not constitute valuable consideration and is therefore legal under Sec. 301 of NOTA.

In 2006, a directive was published in the Federal Register (Vol. 71, No. 116, 34946) instructing the OPTN to "develop policies regarding living organ donors and living organ recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule". It is clear that the value of living organ donation and transplantation is an activity to be encouraged from the perspective of those in need of receiving organs, the medical community, those that reimburse organ transplantation and the government and oversight community.

The live donor does an extraordinary act; lying down on an operating room table, giving up a piece of oneself for another person and placing one's health and safety in the hands of doctors and nurses when there will be no direct medical benefit for the person. Our society (and treasury) gets a great deal of benefit from this form of generosity.

Unfortunately, the pain of recovery from the procedure of removing a kidney (or any other organ) is often not the only form of pain that the donor suffers. Financial pain is also common. Significant financial disincentive to be an organ donor exists in the US. This comes in many forms: lost wages of the donor and family support members, temporary change in the ability to perform one's job during the recovery period, travel costs incurred during the evaluation to be a donor, potential ability to obtain and collect insurance benefits as a consequence of the donation process or in a worse case scenario, permanent disability, need for transplantation or even death.

We have no safety net for those that want to donate organs. Fortunately, kidney donation is relatively safe with a very low risk of death and minimal long-term morbidity, but there are multiple reports in the transplant and lay literature and even more personal anecdotes of significant financial hardship associated with the live organ donation process. This is particularly true for those individuals with personal incomes at the lower end of our financial earnings spectrum. Although the costs of the medical workup are covered by the recipient's payor, for the person without means, the personal savings, family or employers ability to help defray the additional expenses just don't exist.

As a society, we gain much in quality of life from the recipients and financial benefit through the acts of generosity that occur daily through live organ donation. I recently gave a talk at the International Liver Transplantation Society on the "Ethical aspects on live organ donation". During the discussion, there was unanimous agreement that live organ donation was not cost neutral for the donor in any country. Not only did the donation cost an organ (or part thereof), it usually cost some sum of monies from lost wages and out of pocket expenses. In this forum, the international community felt that we should do better.

In fact, if we can create a model that minimizes the personal cost to the live organ donor (family), we are likely to see more donors from people at the lower end of the financial spectrum step forward to donate for the benefit of their loved ones. An important point of this goal is that the projected cost of making organ donation cost neutral would not be more than the savings to the system as it costs more to keep someone on dialysis than to transplant them.
The major areas to be addressed should include:
1) health insurance/automatic Medicare eligibility in the event that the organ donor develops a medical condition requiring treatment as a consequence of the donation;
2) short term disability and life insurance to benefit the families of donors that either die or are unable to return to work after donation.
3) reimbursement for out of pocket expenses. A variety of methods could accomplish this end, but most would require authorization to assign these costs to the Medicare cost center at the transplant center.

The financial benefits of transplantation to our society are real. The media is fond of stating that there are not enough organs available in the US and that people are leaving this country to obtain organs from overseas. Within all ethical means, we need to increase the organ availability for those who would benefit from organ transplantation. Yes, we

need to continue to develop new methods and systems that increase the numbers of organs from deceased donors. But a simple look at of our live donation system reveals that presently, we penalize the person that wants to donate an organ. As a society, we can and should be able to do better. The savings to the system by removing more people from dialysis makes the continuation of financial disincentive to live organ donation absolutely inexplicable.

Mr. CLAY. Thank you so much.

Let me now recognize Ms. Dunn. You may proceed with your testimony, please.

STATEMENT OF SUSAN DUNN

Ms. DUNN. Thank you, Chairman Clay, Mr. Lynch. My name is Sue Dunn, and I am president-elect of the Association of Organ Procurement Organizations [AOPO]. I am also president and CEO of Donor Alliance, the non-profit, federally designated organ procurement organization [OPO], that serves Colorado and most of Wyoming.

It is my privilege to offer you my perspective today as a donation professional, one of thousands across the country who honor the decisions of deceased individuals and families to save lives as organ and tissue donors.

OPOs are responsible for the identification and care of organ donors and their families, organ recovery and preservation, transportation, and data collection regarding deceased organ donors. OPO's staff work with donor families and educate medical staff and the general public about organ donation. The priority of OPOs has always been to respect donors' wishes and to provide support to donor families during the most difficult time of their lives.

Since starting my career as a donor coordinator over 23 years ago, I have been continually inspired by the capacity of individuals and families to give the gift of life. Thanks to these organ donors and the partnership of Federal and State government, OPOs, the Nation's largest hospitals and transplant programs, Colorado, Wyoming, and the rest of the Nation have seen unprecedented gains in saving lives through transplantation.

In the donation service area that I am responsible for of Colorado and Wyoming, the number of deceased organ donors increased by 40 percent from 2003 to 2006, and this also marked with a 25 percent increase nationwide.

Given that only 1 percent of all hospital deaths occur under circumstances that medically allow for organ donation, every single donation opportunity is crucial. Several factors have helped Colorado, Wyoming, and the rest of the Nation convert more opportunities into gifts of life than ever before.

First, we made the responsibility for every organ donation opportunity a shared one, with Government, donor hospitals, OPOs, transplant centers, medical examiners, and all others equally being accountable for success. In Colorado and Wyoming, hospitals took ownership of their critical role in the process by working collaboratively with us in adopting nationally recognized best practices.

Second, our focus on data-driven performance measures has helped all parties involved focus on every donor and every organ every single time. When the Organ Donation and Transplantation Breakthrough Collaborative set goals of 75 percent conversion rate and 3.75 organs transplanted per donor, I have to say we were all in disbelief. The bar was set very high. But no more.

I want to share with you our experience at Donor Alliance. Over the past 2 years, our conversion rates have consistently been at 80 percent. That means 8 out of every 10 eligible donor's organs are transplanted. Many factors have contributed to this success: an

early referral system, trained family support coordinators, an effective donor registry, an organizational focus of placing all organs in active local transplant programs.

The organs transplanted per donor metric has proven a bit more of a challenge. In certain demographic groups we are placing 4.0 organs per donor; however, our overall average is only 3.3. The demographic mix, the nature of injuries, and the overall health of the donor does impact organ placement. Rigorous post-donor reviews are conducted with our staff and our medical director to see how we can improve those practices after every case.

Third, OPOs have benefited from the active involvement of hospital leadership. By developing relationships with senior leadership at large donor hospitals, hospital systems, and the State hospital associations, donation becomes an institution-wide effort, not simply the responsibility of critical care nurses or physicians. Most hospitals now include some sort of measure of donation on their organizational dashboards that are circulated to the executive team, as well as their boards of directors.

With this momentum and extraordinary results, the OPO community has worked to sustain and expand the efforts of the Joint Commission accreditation standards, implementing the Centers for Medicare and Medicaid services conditions of participation for OPOs, spreading the Collaborative, and championing the revised Uniform Anatomical Gift Act. The UAGA, which, as of September 21st, had been adopted by 20 States and had legislation pending in others, the UAGA represents a significant, far-reaching effect, and it is important to note that it only relates to deceased donors.

In general, the UAGA incorporates a number of important features. Most importantly for this discussion today is the creation of State donor registries, which allow individuals to enroll in State-authorized computer donor registries. Most of these are managed under the Department of Motor Vehicles.

Donor registries have several key benefits. First, by recording one's wishes in a searchable data base, it makes sure that the donor's wish is honored. Second, we also know that obtaining consent at the very front end of the case allows us to move to organ placement in a much quicker fashion.

In Colorado and Wyoming, along with other parts of the United States, more than 40 percent of our organ donors are off of the registry, and 50 percent of our tissue donors.

To sum up, Colorado and Wyoming and the rest of the Nation have benefited from the concerted efforts of the past several years. As you know, an increase in donor organs not only saves lives, but also saves the Federal Government millions of dollars in dialysis and other health care costs.

Thank you for helping us sustain and build our mission to honor donors' wishes, support donor families, and save lives.

[The prepared statement of Ms. Dunn follows:]

STATEMENT BY

SUSAN DUNN

PRESIDENT-ELECT

ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS

PRESIDENT AND CEO

DONOR ALLIANCE, INC.

BEFORE THE

INFORMATION POLICY, CENSUS, AND NATIONAL ARCHIVES SUBCOMMITTEE

OVERSIGHT AND GOVERNMENT REFORM COMMITTEE

SEPTEMBER 25, 2007
2247 Rayburn HOB
2:00 P. M.

Introduction

Congressman Wm. Lacy Clay and Members of the Subcommittee,

I would like to thank you for this opportunity to testify before the Subcommittee today on the issue of saving lives and I applaud the Subcommittee for bringing these important issues before the public. My goal is to share with the Subcommittee an organ procurement organization's perspective on donation.

My name is Sue Dunn. I am the President-Elect of the Association of Organ Procurement Organizations, otherwise known as AOPO. I am also the President and CEO of Donor Alliance, Inc., the federally designated organ procurement organization (OPO) that serves the donation service area of Colorado and most of Wyoming.

AOPO represents and serves all 58 federally designated OPOs through advocacy, support, and development of activities that will maximize the availability of organs and tissues and enhance the quality, effectiveness, and integrity of the donation process. AOPO is a professional organization that is dedicated to honoring donors and their families and meeting the needs of waiting recipients by providing education, information, research, and technical assistance to OPOs, and facilitating communication and understanding among OPOs, other healthcare organizations, and federal agencies to promote the goals of organ and tissue donation.

An OPO is a not for profit organization, by statute, that is federally designated by the Department of Health and Human Services. OPOs are responsible for identification and care of organ donors and their families, organ retrieval, organ preservation, transportation, and data follow up regarding deceased organ donors. OPO staff work with donor families, and educate medical staff and the general public about organ donation.

The Crisis

As of September 21, 2007, just this past Friday, nearly 100,000 Americans were waiting for a life saving organ transplant. Approximately 18 of these patients die every day while waiting for an organ that never comes. The growing divide between the number of people waiting for a transplant and the number of available organs has become a national health crisis. Most organs available for transplant come from deceased donors. In 2006 there were 22,201 transplanted organs from deceased donors and 6,729 from living donors. A deceased donor may donate up to seven solid organs in addition to bone, tissue, skin and eyes which can save or improve the lives of up to 50 people. Since each donor represents the potential of saving or improving 50 lives it means that maximizing the gift from every donor, every time is of extreme importance.

Extraordinary Results and Improvements

A National Experiment

Since the fall of 2003, an extraordinary development has occurred as the number of donors and the number of organs transplanted reached historic record increases as well as absolute levels. The Department of Health and Human Services joined with key national leaders and practitioners from the Nation's transplantation and hospital communities in 2003 to launch the Organ Donation Breakthrough Collaborative. The Collaborative was intended to dramatically increase access to transplantable organs. The purpose of the initiative was clear, measurable, ambitious, and achievable:

> *Committed to saving or enhancing thousands of lives a year by spreading known best practices to the Nation's largest hospitals to achieve organ donation rates of 75 percent or higher in these hospitals.*

This major commitment by all parties focused on the sharing of accountability by all sectors to increase donation. The focus is on the application of quality improvement, team-based approaches to this important endeavor and the increased involvement of the leadership of all organizations. The results have been impressive. Clearly, the United States is far from maximizing its supply of available organs from deceased donors. In 2002, only 6,617 (about 46 percent) of an estimated 14,000 potential donors donated organs. By 2006, however, the number exceeded 8,000.

Through a case study approach, it was determined that the successful programs all had

specific overarching principles and implemented effective practices that could be learned and replicated across the country to increase the number of organs available for transplantation. The Organ Donation Breakthrough Collaborative helped OPOs and their chosen large hospitals to close that gap rapidly. Multidisciplinary teams composed primarily of critical care nurses and OPO staff participated in intensive learning sessions and action periods. Participating teams achieved significantly higher organ donation rates.

AOPO's national study covering 1997-1999, published in the *New England Journal of Medicine* in 2003, documented that about 47 to 49 of every 100 medically suitable donors actually donated one or more organs. By 2006, that number had risen to around 63 to 64 percent. The national goal of 75 percent continues as a goal for all healthcare organizations.

Achieving the Collaborative's purpose of an average donation rate of 75 percent in the Nation's 200 largest hospitals saves or enhances thousands more lives each year. In 2002, the year before the Collaborative began; the number of organ donors was 6,190. In 2006 – the number of organ donors was 8,010. The first six months of 2007 show a continued upward trend for the number of organ donors on course to reach approximately 8,110 donors. (Beginning in 2004 there was a 10.8% rise in the number of organ donors as compared to the previous year, in 2005, there was an additional 5.9% increase.)

Organs Recovered and Transplanted for Each Donor is Also Critical

The number of organ donors is obviously important but so is the number of organs that are transplanted per donor. To increase those numbers, a second National experiment, the Organ Transplantation Breakthrough Collaborative was launched. Based on the same principles as the earlier experiment, this program involved members of transplant centers, donor hospitals, and the OPOs to form their multidisciplinary teams.

The teams focused on the effective practices of high performing transplant centers and began to share and implement those across the country. From 1999 through 2002, the average number of transplants per month was 1,616. In 2004 that number rose to 1,825 and continued its rise in 2005 and 2006 (1,940 and 2,039, respectively). Focusing on the 2006 numbers as compared to the 2002 numbers it is apparent that the number of lives saved increased substantially. Over the course of the year, greater than 5,000 additional lives were saved due to the increase in number of organs transplanted.

This gain, however, has occurred because of the huge increase in donors, unfortunately not matched to date by a corollary increase in the number of organs recovered and transplanted per donor. The challenge continues.

The 2006 Revised Uniform Anatomical Gift Act (UAGA)

With the organ donation crisis continuing to grow, AOPO undertook a review of the anatomical gift laws of fifty-four different jurisdictions, all of which had in place the

original 1968 UAGA or its 1987 revision. The findings were striking as the Association found that there were many issues with the existing state laws:

- *The anatomical gift laws were not uniform.*
- *The 1968 and 1987 versions of the UAGA failed to address the roles of OPOs.* Since the late 1980s, OPOs have administered the process of assessing and obtaining authorization for anatomical gifts. The OPOs, under federal law, are also responsible for assuring that anatomical gifts are properly managed, recovered, and allocated according to the national waiting list that is maintained by the federally mandated OPTN.
- *There was no standard definition of a donor registry, and no core requirements for their establishment or function.*
- *Healthcare agents or proxy holders under a durable healthcare power of attorney were not entitled to authorize post-mortem organ donation under the 1968 and 1987 UAGAs.*
- *The 1987 UAGA explicitly provides that no other person may revoke a document of gift and that the assent of no other person is required for a gift to be valid.* Although this was explicit in the 1987 language, some OPOs and hospitals had failed to follow the existing law so AOPO and others sought stronger and more clearly defined language to reinforce the intent of the document of gift.

After fully defining the issues with the existing laws, AOPO approached the National Conference of Commissioners on Uniform State Laws (NCCUSL) to see if it would be willing to work on another revision. As Howard J. Swibel, President of NCCUSL, stated, "Rarely do we as virtual legislators have the opportunity to literally save people's lives. This is such an opportunity, and we must seize it in earnest, since thousands are waiting for life-saving organ transplants."

The revised UAGA represents a significant, far reaching event. It is important to note that it relates only to deceased donors. Like prior versions, the centerpiece of the 2006

UAGA is the concept of "first-person" consent, under which no other person can alter the individual's decision to donate. The 2006 UAGA expressly bars a person from "making, amending, or revoking" an anatomical gift if that was the donor's wish.

The 2006 UAGA facilitates donation by expanding the list of individuals who may make an anatomical gift on a donor's behalf both during the donor's life and thereafter. The Act also expressly provides for the making of an anatomical gift on a donor registry, in addition to donor cards and driver's licenses. In time, donor registries may become the primary way people choose to make their anatomical gift known. The Act allows for the appropriate state agency to establish, or contract for the establishment of, a donor registry. It also sets forth three criteria for a well designed donor registry:

- The registry will allow a donor or other authorized person to make a gift on the registry by way of statement or symbol,
- The registry is accessible to all OPOs to determine whether an individual at or near death has made, amended, or revoked an anatomical gift,
- The registry must be accessible to donors, authorized persons acting on their behalf, and OPOs on a 24/7 basis.

If a decedent dies without having made an anatomical gift during life, the 2006 UAGA provides that a gift can be made on the decedent's behalf by his or her spouse, adult children, parents, adult siblings, grandparents, decedent's adult grandchildren, the individual who was acting as the decedent's agent under power of attorney at the time of death, and as well as any adult who exhibited special care and concern for the decedent. If none of these people are available, the gift may be made by the person having the

authority to dispose of the body of the decedent (i.e., coroner, medical examiner, hospital administrator, or government official).

Under the 2006 UAGA, any member of a class (such as all of the adult children of a decedent) may make a gift if he or she is unaware of any objections by other members of the class. If an objection is known, then the gift can only be made by a majority of the class members. The 2006 UAGA also prioritizes the anatomical gift's purpose (transplantation, therapy, research, or education).

In general, the 2006 UAGA incorporates a number of important new features that will increase organ, tissue and eye donation. The 2006 UAGA can play a major role in meeting the needs of those waiting for a life saving organ but only if all the state legislatures adopt the new language. As of September 21, 2007, the 2006 UAGA had been adopted by twenty states and legislation is pending in at least eight other states. Our Association and its members continue to work hard across the Nation in achieving broad Sate acceptance and incorporation of this important set of model legislative provisions.

DonorNet2007

Since inception of the OPTN in 1986, OPOs, transplant centers and histocompatibility labs have relied upon the telephone and the fax machine to make and review organ offers, collect and assess donor data and labs results, and ultimately accept or refuse a limited supply of transplantable organs. This voice and paper-based, work-intensive process

performed repetitively and usually under great pressure had allowed for some inaccuracies, miscommunications and human errors.

Patient safety, efficiency, accuracy and equity were foremost in the minds of those dedicated to the redesign of DonorNet and the implementation of an electronic organ placement system for the Nation. The new system allows transplant centers to quickly indicate to the OPO whether they *are* or *are not* interested in accepting the organ, so that the OPO coordinator's time can be dedicated to communicating with those centers that *are* interested.

DonorNet 2007 supports a central electronic environment that enables OPOs to make multiple, simultaneous organ offers according to policy, and provides qualifying transplant centers equal and immediate access to uniform donor data and lab results. The new system became available to the community in the fall of 2006 and became fully implemented in January 2007.

To ensure that OPOs and transplant centers' needs and concerns were addressed in the design and roll-out of the new system, the OPTN/UNOS Operations Committee established the Electronic Organ Placement Working Group, whose members include physicians and surgeons, organ and transplant coordinators and administrators from a variety of transplant centers, organ procurement organizations and histocompatibility labs, as well as representatives of the AST, ASTS, AOPO and NATCO.

The involvement of OPOs in support of the development and implementation of this major information technology has been critical. The bottom line effect has already been seen in reductions in the placement time for life saving organs.

Organ Donation and Recovery Improvement Act

Congress has the unique opportunity to assist in addressing financial disincentives to living organ donation, better coordinating organ donation in hospitals, and improving the science of donation. We ask you to support an initial appropriation of $2 million for Public Law 108-216 which is in the FY 2008 Labor, Health and Human Services, and Education appropriations bill. The law was signed in 2004 and was authorized for five years. The legislation is in the fourth year of its five year authorization. This is the last opportunity to obtain funding for implementation of the critical programs that can save lives.

As you may know, an increase in donor organs not only saves lives, but also saves the federal government millions of dollars in dialysis and other health care costs. In the case of living kidney donation, Medicare would avoid direct dialysis costs exceeding $55,000 per year for each patient transplanted.

The need for funding this year is more critical than ever. The Division of Transplantation has received cuts or level funding for the past four fiscal years. These cuts are in spite of the Office of Management and Budget's goal of doubling the number of transplanted organs by 2013. We share the opinion, along with many in Congress and the Administration, that enactment of the Organ Donation and Recovery Improvement Act of 2004 was a very positive step toward meeting the needs of people waiting for a

transplant. But, only with adequate appropriations will this bipartisan legislation allow the federal government, states, and other public and private entities to expand their current organ donation efforts and create new, effective organ donation programs.

Conclusion

Organ donation has seen an amazing increase over the past number of years. The spectacular force of positive action has been created by bringing together professionals from the OPOs, the donor hospitals, and the transplant centers. Other positive steps have been taken through legislative and policy efforts as well as improvements in the use of technology. The focus remains on the donor, the donor family and honoring their wishes. With the continued support of Congress, the Federal government and the stakeholders, we will be successful in saving more lives through donation and transplantation.

I would like to thank the Subcommittee for the opportunity to present the organ procurement organization perspective on the topic at hand and will look forward to answering any questions you have.

Mr. CLAY. Thank you so much, Ms. Dunn, for your testimony.

Now we will go to Dr. Callender. Please proceed.

STATEMENT OF CLIVE O. CALLENDER, M.D.

Dr. CALLENDER. I am Dr. Clive Callender, transplant surgeon at Howard University Hospital, and the founder and principal investigator of MOTTEP.

MOTTEP is addressing the No. 1 problem in transplantation today, the shortage of organ donors. Because of this shortage, nearly 20 people die every day, and taxpayers spend $40,000 per patient per year for kidney dialysis treatments. The MOTTEP program provides organs, which saves lives and over time decreases health care expenditures on dialysis by $235 million for kidneys, alone.

Since 1982, 25 years ago, we have participated in the growth and development of a national donor education program which relies on a grassroots strategy that emphasizes community education and empowerment, requiring the community to be an efficient and economically appropriate change agent.

The methodology we use provides compelling evidence of the efficiency of a community-based, grassroots approach, delivering a two-pronged message aimed at increasing donation rates and promoting the adoption of healthy lifestyle behaviors and practices.

The key for its success is utilizing a methodology that emphasizes the use of culturally sensitive and ethnically similar community individuals who are transplant recipients, donors, and their family members as messengers.

When we started this effort in the African American community in 1982, it was stated to me that Blacks don't and won't donate organs. Ten years later, our success in the African American community resulted in the conceptualization of MOTTEP and expanded our effort into all minority populations. Ten years after this, as table one demonstrates, minorities now donate in proportion to their population distribution.

When we look at our second table, the Scientific Transplant Registry has data that demonstrates that when MOTTEP sites are involved, when compared and contrasted with non-MOTTEP sites, we have significantly improved donation rates when compared to regions in which there were no MOTTEP sites.

Our final table shows that the number of donors, the organ donors per million, and donation percentages have statistically increased in all minority groups. In fact, while minorities represent 25 percent of the American population, the number of minority donation percentages has increased over that 10 year period from 15 percent to 30 percent.

Since 50 percent of all kidney transplants' survival ranges from 5.3 to 12.2 years, and most more than 9 years, it is clear that the financial benefit to the Government supporting a national donor education program such as we talk about would save millions of dollars. We break it down. Since dialysis costs in excess of $40,000 per patient per year, much of which are taxpayers' dollars, and transplants break even after 3 years, this would provide an average savings of at least $30,000 per year for each year the organ

survives over 3 years. Assuming an organ survival rate of 6 years, each donor organ would save at least $135,000 per donor.

Assuming a kidney transplant's cost after 3 years would be $10,000, looking at the graphics that we just talked about, it is clear that the cost/benefit ratio is one that is a worthy investment when we consider the benefits greatly outweigh the under-funded support that is provided to national donor education programs.

Now, these data are based upon the current census that identifies 25 percent of the American population as minorities. The MOTTEP goal is by 2010 to have 35 percent of the donors being minorities and to have African Americans and Latinos to increase from 41 organ donors per million to 50 organ donors per million. Should this occur, we would recover 1,750 minority donor organs and save the Government $236 million.

While MOTTEP has received a total of $16 million from the Federal Government between 1992 and now, none of these dollars have been allocated for organ donation after 2007. This would mean this unique program, which has made a national contribution to the donor shortage, would cease to exist after mid-year 2008. Currently, MOTTEP exists at 11 sites, only 5 of which are partially funded. To optimize this unique community grassroots education program, funding for 15 to 25 sites would require $3 million to $5 million per year for an additional 5 years, a small amount when compared to the $236 million saved from kidney transplants, alone, and the more than $1 billion saved when kidneys, livers, hearts, and other organs are combined.

[The prepared statement of Dr. Callender follows:]

National
MOTTEP
minority organ tissue transplant education program
Clive O. Callender, M.D. F.A.C.S.
Founder and Principal Investigator

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
THE INFORMATION POLICY, CENSUS, AND NATIONAL ARCHIVES SUBCOMMITTEE, OVERSIGHT AND GOVERNMENT REFORM COMMITTEE

"ORGAN DONATION: UTILIZING PUBLIC POLICY AND TECHNOLOGY TO STRENGHTHEN ORGAN DONOR PROGRAMS"

Testimony of
Clive O. Callender, MD, FACS
September 25, 2007

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"Love Yourself, Take Care of Yourself"

"Organ Donation: Utilizing Public Policy and Technology to Strengthen Organ Donor Programs" Testimony – Clive O. Callender, MD, FACS

The number one problem in transplantation today is the shortage of donors. More than 96,000 people today are on transplant waiting lists. Nearly 25,000 transplants are performed annually leaving an organ donor recipient disparity of 65,000. This disparity results in nearly 20 deaths/day at least seven of which are African Americans (A.A.). In order to answer the questions, what has happened to organ donations in the A.A. population, and how it compares with donations in other ethnic groups? I will share three decades of work (1982-2005) in the African American community which have culminated in the development of a methodology which has narrowed the A.A. donor gap, and which has the potential to help narrow or eliminate other minority health disparities. African Americans represent 13% of the American population, but make up 35% of those on kidney transplant waiting lists. In 1982 when we began our first African American donation campaign, it was stated that Blacks "don't and won't" donate organs for transplant purposes. Then the A.A. donations rate in organ donors per million (O.D.M.) was eight compared to eighteen O.D.M. in the Caucasian population. We then began the D.C. Organ Donor Program (DCODP) in conjunction with Howard University and the National Kidney Foundation of the National Capital Area between 1982 and 1990 with five hundred dollars from Howard University. This program began with a two hour community focus group session with forty District of Columbia residents and included one kidney donor and one transplant recipient. Upon completion of these sessions, we identified the five commonest obstacles to organ donation in the District of Columbia. They were: 1). Lack of transplant awareness, 2). Religious myths and misperceptions, 3). Medical distrust, 4). Fear of premature death after signing a donor card, 5). Racism. The second important outcome of those focus sessions was that while only two of forty had signed donor cards at the beginning of the session, forty of forty donor cards were signed by the end of the session. This led us to form the DCODP in August of 1982; this was a grass roots effort to change behavior in the District and the surrounding Metropolitan Washington area. The cultural and ethnically sensitive presentations to the community were directed at overcoming the five obstacles identified above

By 1990 the number of donor cards signed at the D.C. Motor Vehicle Office increased from 25/month to 750/month and the number of A.A. organ donors in the District of Columbia

doubled. Because of the success of the DCODP, the Dow Chemical Company (1986-1992) sponsored my involvement in national media tours in fifty cities to increase awareness about the need for more Black donors. This initiative merged the community grass roots, face-to-face interaction and mass media approach. Gallup Polls done in 1985 and 1990 identified that the number of Blacks aware of the highly successful nature of transplants and the number of Blacks signing donor cards had trippled during this five year period secondary to this Dow Chemical Company Take Initiative Program directed at the A.A. population. This led us to conceptualize The National Minority Organ Tissue Transplant Education Program (MOTTEP) in 1991 to use this successful community grass root and mass media approach in all minority groups (African American, Latino/Hispanic, Asian, Pacific Islander, Alaskan Native, American Indian).
Congressman Louis Stokes, Secretary of Health and Human Services, Dr. Louis Sullivan and Dr. John Ruffin then intervened and encouraged us to seek NIH funding to allow for the development of fifteen community grass root programs in fifteen cities across the United States (Anchorage, Alaska; Birmingham, Alabama; Los Angeles, California; Washington, D.C.; Miami, Florida; Atlanta, Georgia; Honolulu, Hawaii; Chicago, Illinois; Detroit, Michigan; Albuquerque, New Mexico; Brooklyn, New York; Cleveland, Ohio; Nashville, Tennessee; Houston, Texas; and Richmond, Virginia).

WHAT IS THE NATIONAL MOTTEP MODEL?

The National MOTTEP model was conceptualized based upon the successes of our previous African American education programs such as the local DC Organ Donor Project (DCODP), 1982-1988 and nationally, the DOW Chemical Company Take Initiative Program (DOWTIP), 1986-1992. These successes led us to utilize their successful methodologies with the Latino-Hispanic, Native American, Alaskan Native and Asian-Pacific Islander populations as the National Minority Organ Tissue Transplant Education Program (MOTTEP). This model combines media campaigns and grass roots efforts to disseminate a two-pronged message: preventing chronic diseases particularly hypertension, renal failure, diabetes and obesity while simultaneously increasing organ donation rates. The following is a summarization of the national impact of MOTTEP.

A 25 YEAR DATA ANALYSIS OF A NATIONAL DONOR EDUCATION PROGRAM

Since 1982 we have participated in a national donor education program emphasizing community education and empowerment requiring the community to be an efficient change agent. As described above, the grass roots approach is combined with mass media aimed to: 1) increase organ donation rates and 2) adopt healthy lifestyle behaviors. The methodology utilizes culturally sensitive and ethnically similar community individuals who are transplant recipients, donors and their family members as messengers. Three distinct eras are evident.

Era I – 1982 –	**Present Era II – 1995-2005**	**Era III – 1995-2005**
African American Impact	Hispanic/Latino Impact	Asian Impact

A review of National African American data demonstrated a change from 8 organ donors/million (1982) to 40.8 organ donors/million (2002). A 50 city campaign Gallup Poll (1986-1992) demonstrated a tripling of Black awareness of the success of transplants and the number of Blacks signing donor cards. Locally, donor card signings increased from 25/month to 750/month (1982-1988) and Black donors in the District of Columbia doubled by 1988. Tables 1-3 illustrate increases in donors, donation rates, organ donors/million and the impact on donation rates in cities with a national structured effort versus areas those cities without a national effort.

Minorities Donate in Proportion to their Population Distribution (Table 1)

Ethnicity	**Population Percentage (2003)**	**Donation Percentage**
Black	12.7	12.6
Hispanic	10.9	12.2
Asian	3.8	2

Cadaveric Donors per 1,000 Evaluable Deaths and Number of Donors by Ethnicity and OPO's, 1995-1998

	MOTTEP		Non MOTTEP		(Table 2)
Ethnicity	**Donation Rate**	**Donors**	**Donation Rate**	**Donors**	**p-value**
White, Non Hispanic	59.3	4,928	59.2	11,279	0.02
White, Hispanic	106.9	1,055	47.4	886	<.01
Black	43.4	1,263	32.9	1,286	<.01
Other	50.7	228	42.4	272	<.01

(Table 3)	Number of Donors		Donors/Million		Donation Percentages	
Ethnicity	**1990**	**2000**	**1990**	**2000**	**2000**	**2005**
Black	659	1373	22.4	40.8	11.2%	14%
Hispanic/Latino	518	1319	22.9	40.2	11.2%	13.2%
Asian	73	278	10.3	26.2	2.7%	2.6%
Minority Donor Total					25.1%	30% (29.8%)

National MOTTEP's PAST ACCOMPLISHMENTS

In the past, National MOTTEP® has used several intervention mechanisms that, because of their success, will be used our expanded programs. First, MOTTEP® has made extensive use of the media in order to change minority behavior regarding organ and tissue donation and about healthy living. For example, media impressions between 1993 and 2006 have increased from 30 million to more than 8 billion respectively. By reaching an average of one million community persons annually, National MOTTEP has empowered communities to meet the challenge head on by participating in the donor process and adopting healthy lifestyles to prevent the need for transplantation. The figure below lists some milestones throughout MOTTEP's history. Through the expanded efforts, MOTTEP anticipates creating new milestones.

MOTTEP Milestones

I.A. 1991 – 1993

- MOTTEP Conceptualized in 1991 – Callender/Smith.
- MOTTEP Concept and Strategic Plan – Sponsored by Congressman Louis Stokes – 1992.
- MOTTEP authorization approved by Congressional Appropriations Committee – May 1992.
- MOTTEP legislation authorized by President Bush in the Fall of 1992.
- Development of an African American Strategic Plan.
- Development of an Hispanic Strategic Plan.

I.B. 1993 – 1995

- First MOTTEP contract from office of the NIH Director, Dr. Bernadine Healy, and Dr. John Ruffin, Associate Director, NIH Office of Minority Health Research – 1993 to 1995.
- Development of MOTTEP survey evaluation tool – Pre & Post MOTTEP presentations.
- Organ Donation: The Problem; MOTTEP: The Solution – This publication chronicles MOTTEP's evolution.
- Development of National African American Transplant Strategic Plan.
- Development of National Latino Transplant Strategic Plan.
- Development of MOTTEP "Give to Save" Logo and Theme Song.
- Appeared on the Oprah Winfrey Show, BET, CBS Evening News – all national TV shows with audiences exceeding 9 million.
- "Focus on Health" weekly radio talk show on WOL (Washington, DC and Baltimore, MD) from 1993 to 1995.

II. 1995 to 1999

- National Minority Transplant Hall of Fame Inaugurated – September 1, 1996.
- Inaugurated National Minority Donor Awareness Day – August 1, 1996.
- Evaluation reports on findings of the program effectiveness study using data from matched sets of pre- and post- questionnaires for all youth and adult participants showed that: 1) statistically significant increases ($P<0.5$) occurred in the levels of knowledge on organ/tissue

donation; and 2) participants significantly more likely to state their willingness to become organ/tissue donors after hearing the MOTTEP presentations.

- Implementation of the First National Model Minority Transplant Strategic Plan – 1995.
- Implementation of the First National Latino Transplant Strategic Plan – 1995.
- Developed the First National Asian-Pacific Islander Transplant Strategic Plan – 1995.
- Developed the First National Minority Community Transplant Information Resource Center – 1995.
- Under the influence of MOTTEP, African American organ donors per million (O.D.M.) increased from 8 in 1982 to 20 O.D.M. in 1995 and to 28 O.D.M. in 1998.
- Likewise, Hispanic/Latino O.D.M. increased from 9 in 1994 to 18 in 1998.
- During this same time period, Asian/Pacific Islander O.D.M. doubled.
- African American/Black recipients of African American/Black organ donors increased from 3% in 1985 to 23% in 1998.
- Total Number of Media Impressions from July 1, 1995 – 1999; 3 Billion.
- Total Number of People Reached Through Face-to-Face Presentations since July 1, 1995 equaled 4 Million.
- Generated 492 publications and presentations; 46 academic publications and 23 videos;
- Total number of requests for materials – 1009.
- Organ and Tissue Donations Directly Linked To MOTTEP Presentations As of June 1, 1999: 38 donors from MOTTEP presentations. Birmingham – 2 donations (4/2/98 and 1/3/99); Atlanta – 2 donations, Detroit – 2 donations (1/29/99 and 5/28/99), Honolulu – 1 donation (1/99), Nashville – 1 donation (5/12/99), Chicago/NW Indiana – 30 donations (since beginning of grant in 1995).
- Total number of pre/post surveys (youth and adult) – 7048.
- The number of National or International – publications on MOTTEP and minority transplant education efforts since 1995 is thirty.
- Two Institute of Medicine presentations 1999; one presentation to Secretary Shalala's "Forum on Liver Allocation and Organ Donation" – 1996; two MOTTEP presentations (testimonies) before the Congress of the United States (April 18 and June 18, 1999).

- Development Of The First National Minority Donation Education effort – Community-based with a grass roots and multimedia combined approach – 1993.
- Produced and Hosted "Focus on Health" – a weekly two-hour radio call-in talk show on WOL (Washington, DC and Baltimore, MD) – 1993 to 1995.
- MOTTEP modus operandus identifies – donors and donor families, transplant recipients, transplant candidates of local community origin and ethnically and culturally similar and sensitive – as the most effective messengers – 1993 to 1995.

Other "Firsts" Accomplishments Include (1993-1995):

- First to identify community as the most potent and cost efficient "change agent" – 1993 to 1995.
- First to emphasize the importance of the combination of "Prevent the Need" and "Increased Need for Organ/Tissue Donors" as the most efficient mode of community outreach and education (1993-1995).
- Implementation of the First Model National Minority Transplant Strategic Plan.
- Implementation of the First National Latino/Hispanic Transplant Strategic Plan.
- Developed the First National Asian and Pacific Islander Transplant Strategic Plan.
- First to identify community as the most potent and cost efficient "change agent".
- First to emphasize the importance of simultaneously promoting the messages of "Preventing the Need" and "Increasing the Number of Organ/Tissue Donors" as the most efficient mode of community transplant-related outreach.
- First to take the fruits of the first minority donor education programs of the District of Columbia Organ Donor Program (DCODP) and the Dow Chemical Company Take Initiative Program (DOWRIP), and apply them to all ethnic minority groups via funding by the National Institutes of Health – Office of Research on Minority Health and the National Institutes on Diabetes and Digestive and Kidney Diseases (1993).
- First to inaugurate National Minority Donor Awareness Day (August 1, 1996).
- First to establish the National Minority Transplant Hall of Fame (September 1, 1996).

As previously mentioned, National MOTTEP was the first program of its kind in the country that was designed to: 1) educate minority communities on facts about organ/tissue transplants and how to maintain the health of key organs and tissues; 2) empower minority communities to develop programs to increase awareness; and 3) increase minority participation in organ/tissue transplant endeavors including signing organ donor cards, encouraging family discussions and involving parents in the decision to retain the health of kidneys, livers, hearts, lungs and other organs.

National MOTTEP was also one of the first organizations in the country to work to expand its original grassroots efforts to include a health promotion and disease prevention component that exclusively targeted youth as well as adults. The disease prevention aspect was added to decrease the disproportionate rate of hypertension, diabetes and other diseases that affect minority populations. More specifically, a comprehensive, intensive outreach campaign focused upon uncontrolled or untreated diabetes mellitus, hypertension, proper nutrition, increased physical activity and avoiding the use of alcohol and other substances by minorities.

However, National MOTTEP's primary activities have remained the design, implementation, and evaluation of educational programs for national use in order to increase the number of minority Americans who take active roles in organ and tissue donation and who hold family discussions. National MOTTEP also provided leadership in educating the public about how to maintain sound organs. To support these campaigns, MOTTEP utilized the following strategies: Established networks of speakers, (i.e., youth, parents, celebrities, transplant recipients, donor family members, transplant candidates, health care professionals) who were available to religious and community-based organizations to promote organ and tissue health; Identified, accessed and utilized print media and radio technology to increase awareness among minority audiences of organ and tissue health; Supported and sponsored national and local forums which targeted public, private and community leaders who then disseminated information to minority communities on organ and tissue health; Established a library of audiotapes, videotapes, print and other materials which were made available for duplication; Followed up on any media coverage related to organ and tissue health to generate a greater knowledge of issues related to organ/tissue health; and Collaborated with an exceptionally large range of other community-

based organizations in order to implement health promotion and public awareness campaigns at each of the sites in the targeted cities.

MOTTEP of HONOLULU - Accomplishments

The goal of this project is to expand educational efforts across all ethnic, religious and age groups to increase the number of individuals consenting to donate organs and tissues and to increase the supply of organs for waiting transplant recipients through the expansion of a public education program on organ and tissue donation.

The Minority Organ Tissue Transplant Education Program (MOTTEP) is a nationwide program designed to educate ethnic minority communities about organ and tissue donation and transplantation to increase the number of donations from these communities. The Organ Donor Center of Hawaii (ODCH) implemented MOTTEP of Hawaii in 1995. The program currently focuses on Hawaii's local Filipino community which had the highest number of individuals on the organ transplant waiting list (36%) and the lowest number consenting to donation (3%). In 2002, the University of Hawaii – Cancer Research Center of Hawaii (CRCH), in collaboration with ODCH and various Filipino community organization was awarded a five-year grant to continue MOTTEP. Funding of the program will end in June, 2007.

The program's objectives, as it remains focused on the Filipino community and extends its outreach to Hawaiian and Pacific Islander communities, are to:

- Increase the number of individuals designating themselves as organ donors via driver's license, state ID and/or donor card
  Assure that family discussions occur to inform their loved ones of their wishes
- Increase the number family consents for organ and tissue donation
  Increase education and awareness about organ and tissue donation in the community.

Organ Donor Center of Hawaii will continue to focus on Filipino community and plans to expand the MOTTEP to the Hawaiian and Pacific Islander Communities. Currently 49 of the 375 Hawaii residents on the Hawaii Transplant Waitlist are Pacific Islanders, the second largest group after Asians (which include Filipinos) who represent the largest ethnic group in the waitlist. Over the past 3 years, the Hawaiian and Pacific Islander groups represent the third largest potential organ donor group, but the lowest consenting ethnic group.

Since implementation in 1995, Organ Donor Center of Hawaii has been working with in the Filipino community through MOTTEP. The program's success is documented through an increase in the Filipino donor consent from 3% to 27% during that time period. Over the past 3 years, organ donation consent rates among Filipinos have steadily increased: 40% in 2004, 67% in 2005, and 71% in 2006. It is evident that MOTTEP's public education efforts to improve organ donation rates among the Filipino population have been effective and we wish to sustain this success. The result of this successful program is evidenced in increased donor consent in the Filipino community from 3% to 71%.

MOTTEP is a national model that has shown to culturally effective in the Filipino Community and will be adapted and expanded to include other Hawaiian Pacific Islander communities.

Summary:

Since 1982 we have participated in the growth and development of a national donor education program which relies on a grass roots strategy that emphasizes community education and empowerment requiring the community to be an efficient and economically appropriate change agent. **Methodolgy:** The data presented provide compelling evidence of the efficiency of a community-based grass roots approach combined with mass media to deliver a two-pronged message aimed at: 1) increasing organ donation rates and 2) promoting the adoption of healthy lifestyle behaviors and practices. The key for its success is utilizing a methodology emphasizing the use of culturally sensitive and ethnically similar community individuals who are transplant recipients, donors and their family members as messengers. Three distinct eras are evident.

Era I – 1982 – Present	**Era II – 1995-2005**	**Era III – 1995-2005**
African American Impact	Hispanic/Latino Impact	Asian Impact

Results: African American data emphasized here reflects the impact of national education efforts resulting in an increase from 8 organ donors/million (1982) to 40.8 organ donors/million (2002). Regionally, a 50 city campaign Gallup Poll (1986-1992) demonstrates a tripling of

Black awareness of the success of transplants and the number of Blacks signing donor cards. Locally, the number of donor cards signed increased from 25/month to 750/month (1982-1988) and the number of Black donors in the District of Columbia doubled by 1988. Tables 1-3 below illustrate the increases in donors, donation rates, organ donors/million and the impact on donation rates with a national structured effort versus areas without a national effort.

Minorities Donate in Proportion to their Population Distribution (Table 1)

Ethnicity	Population Rate	Donation Rate
White	71.7	72.1
Black	12.7	12.6
Hispanic	10.9	12.2
Asian	3.8	2

Cadaveric Donors per 1,000 Evaluable Deaths and Number of Donors by Ethnicity and OPO's, 1995-1998

(Table 2)

	National Effort		No National Effort		p-value
Ethnicity	**Donation Rate**	**Donors**	**Donation Rate**	**Donors**	
White, Non Hispanic	59.3	4,928	59.2	11,279	0.02
White, Hispanic	105.9	1,055	47.4	886	<.01
Black	43.4	1,263	32.9	1,286	<.01
Other	50.7	228	42.4	272	<.01

(Table 3)

	Number of Donors			Organ Donors/Million			Donation %	
Ethnicity	**1990**	**2000**		**1990**	**2000**		**2000**	**2005**
Black	659	1373		22.4	40.8		11.2%	14%
Hispanic/Latino	518	1319		22.9	40.2		11.2%	13.2%
Asian	73	278		10.3	26.2		2.7%	2.6%

Conclusion: Since the half lives for kidney transplants range from 5.3 (A.A.) to 12.2 (Asian), and 50% of all grafts survive at least 5 years and most more than 9 years, it is clear that the financial benefit to the government supporting a national donor education program such as this would save millions of dollars. Since outpatient dialysis costs are in excess of $40,000.00/yr per patient and transplants break even after 3 years, this would provide an average savings of at least $30,000.00/yr for each year the grafts survives over 3 years. Assuming a graft survival rate of 6 years, each donor (living or deceased) organ would save at least $135,000.00 per donor (1.5 x $30,000.00 x 3 years. Deceased donors provide an average of 3 organs/donor while living

donors provide 1 organ/donor). Assuming out patient kidney transplant costs after 3 years = $10,000.00/yr, looking at the graphics presented above, it is clear that the cost benefit ratio of a model national donor education program such as the one presented here is a worthy investment whose benefits greatly outweigh the under-funded support currently provided.

These data are based upon the current census that identifies 25% of the American population as minorities. The MOTTEP goal is by 2010 to have 35% of the donors being minorities and to have African Americans (A.A.) and Latino O.D.M. to increase from 41 O.D. M. to 50 O.D.M. This would allow for the recovery of 1750 minority donor organs and save the Government 236 million dollars.

While MOTTEP has received a total of $16 million dollars from the Federal Government between 1992 and now. None of these dollars have been allocated for organ donation after 2007. This would mean this unique program which has made a national contribution to the donor shortage would cease to exist after midyear 2008. Currently MOTEP exists in 11 sites. Only 5 of which are partially funded. To optimize this unique community grass roots education program, funding for 15-25 sites would require 3-5 million dollars a year for an additional 5 years.

Literature Cited

1. Organ Donation: Opportunities for Action. Institute of Medical 2006: pp. 195-197, "Community Grassroots Efforts and Minority Population" The National Academic Press.

2. Callender, C.O., Maddox, G.D., "Three Decades of Overcoming the African American Donations Disparity", Nephrology News Issues, 18(12): pp. 39-40, 57, (2004).

3. Callender, C.O. – National MOTTEP® Annual Reports

4. Callender, C.O., Maddox, G.D., Miles, P.V. – "Transplantation and Organ Donation: An Analysis of Ethnic Disparities"; Multicultural Medicine and Health Disparities, McGraw Hill Medical Companies, Chapter 10, pp. 217-322, (2006).

Mr. CLAY. Thank you so much for that testimony, Doctor.

Now we will go to Dr. Crippin. You may proceed.

STATEMENT OF JEFFREY S. CRIPPIN, M.D.

Dr. CRIPPIN. Good afternoon, Chairman Clay, Mr. Lynch. On behalf of the American Society of Transplantation, representing the majority of our Nation's professionals engaged in solid organ transplantation, we applaud your leadership for convening this forum today to focus on organ donation and our Nation's ability to deliver the gift of life to the thousands of patients currently awaiting a life-saving donor organ.

Again, my name is Dr. Jeff Crippin, and I am the immediate past president of the American Society of Transplantation and the medical director of the liver transplant program at Barnes Jewish Hospital in St. Louis.

I would like to focus very briefly on the efforts of our society on a national level, as well as two efforts that we focus on back home in St. Louis.

The American Society of Transplantation knows the education and awareness of patients and physicians, alike, is crucial to the delivery of effective health care. The Society has developed several educational programs to provide updated information on issues regarding organ failure and its complications, the transplant evaluation, and the transplant procedure, itself. We have also crafted a program devoted to the care and maintenance of the transplant after it has occurred.

Through these efforts, the AST strives to minimize and eliminate any questions or confusion that may arise as a patient is considering this life-saving surgery, before and after the transplant.

In our own institution in Missouri at Barnes Jewish Hospital in Washington University School of Medicine, Dr. Amy Waterman, a social psychologist and assistant professor of medicine in the Division of General Medical Sciences, is conducting ground-breaking work examining increased patient awareness regarding kidney transplantation. Dr. Waterman is currently developing living kidney donation materials focusing on racial differences and attitudes about diabetes and organ donations. Part of her work is actually funded by the Health Resources and Services Administration through a grant looking at educating patients at kidney dialysis centers about the availability of kidney transplantation.

The data obtained by Dr. Waterman and her colleagues will hopefully lay the groundwork for similar programs across America as we continue to fight the battle against mis-information and the lack of information regarding this life-saving therapy.

In an effort to reach patients in areas that remain under-served in our State and areas not necessarily knowledgeable about transplantation, I have spent the last 4½ years conducting the patient outreach clinic in rural areas, and particularly in southeast Missouri.

The city of Cape Gerardo is a town of approximately 35,000, as you know, about 120 miles southeast of the St. Louis area. As I have found, for various reasons, many of the town's citizens do not like to leave or travel to large urban settings and often refuse a referral to the big city, in spite of a defined need. My presence has

allowed these patients and their physicians to see the need for solid organ transplantation and simplified their need.

Finally, in 1999 the American Society of Transplantation and other transplant organizations worked closely with Congress to pass and enact legislation providing up to 6 weeks of paid leave for Federal employees seeking to donate a life-saving donor organ. Congressman Elijah Cummings of Maryland spearheaded this initiative in the House of Representatives.

In addition to these Federal laws, the American Society of Transplantation has initiated its own private campaign entitled the AST Employee Leave and Donation Program. The purpose of this campaign is for our transplant physician members to reach out to corporate America and encourage them to amend their employee leave policies to allow adequate time for employees to serve as a living donor. This has resulted in many companies changing their rules and removing a financial disincentive to donation.

Mr. Chairman and members of the subcommittee, the American Society of Transplantation thanks you for the opportunity to participate in today's forum. We applaud and commend your leadership and efforts on this important issue. Of note, the American Society of Transplantation endorsed H.R. 3635 last evening. We look forward to your efforts in getting the bill passed.

The gift of life, though often surrounded by tragic circumstances, can prolong the lives of affected Americans, allowing them to maintain their roles as active and productive citizens of our great Nation.

Thank you.

[The prepared statement of Dr. Crippin follows:]

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Celebrating 25 Years of Promoting Excellence in the Field of Transplantation

Testimony Before The

United States House of Representatives

Information Policy, Census and National Archives Subcommittee
Oversight and Government Reform Committee

"Organ Donation: Utilizing Public Policy and Technology to Strengthen Organ Donor Programs"

Jeffrey S. Crippin, MD
Past President
American Society of Transplantation

Medical Director, Liver Transplantation Program
Barnes Jewish Hospital

Professor of Medicine
Washington University School of Medicine
St. Louis, Missouri

Tuesday, September 25, 2007

Good morning Chairman Clay, Ranking Member Turner and members of the Information, Policy, Census and National Archives Subcommittee of the Oversight and Government Reform Committee. On behalf of the American Society of Transplantation, representing the majority of our nation's professionals engaged in solid organ transplantation, we applaud your leadership for convening this forum today to focus on organ donation and our nation's ability to deliver the "The-Gift-Life" to the thousands of patients currently awaiting a life saving donor organ. My name is Dr. Jeff Crippin and I am the Immediate Past President of the American Society of Transplantation and the Medical Director of the Liver Transplant Program at Barnes Jewish Hospital in St. Louis, Missouri.

The American Society of Transplantation (AST) states in our mission statement, that we are "...an international organization of transplant professionals dedicated to advancing the field of transplantation through the promotion of research, education, advocacy, and organ donation to improve patient care." Our interests and mission are very consistent with the title of today's hearing, "Utilizing public policy and technology to strengthen organ donor programs", and we are pleased that this Subcommittee is meeting here today to discuss and examine how we can strengthen the nation's solid organ transplant system.

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AMERICAN TRANSPLANT CONGRESS 2008
May 31-June 4, 2008
Toronto, Ontario, Canada

In addition to this hearing, the AST would like to applaud Chairman Clay (D-MO), Congressman Dave Camp (R-MI), Congressman Jim Costa (D-CA), and Congresswoman Ileana Ros-Lehtinen (R-FL) for reviving the Congressional Organ and Tissue Caucus. Your leadership in educating and raising the awareness and visibility of transplantation and the "gift-of-life" is greatly appreciated by the entire transplant community. Thank you.

The Bottom Line – Supply Does Not Meet Demand

As others have already outlined before this Subcommittee, the challenge in our field is the fact that over 97,000 individuals are currently awaiting a life-saving donor organ. Approximately 73,000 patients are awaiting a kidney, over 16,000 are awaiting a liver, 2,600 for a heart, 2,300 for a lung, and 1,600 for a pancreas. Between January and June of this year, we performed approximately 14,000 transplants with 11,083 deceased donor organs and 3,200 living donor organs.

Clearly the math is not difficult to understand why meeting patient's needs are so difficult in this environment of scarce resources. It also speaks to the fact that protecting a patient's life saving donor organ is critical. Optimal care for transplant recipients is crucial to their long-term survival. The medical problems facing the transplant patient are complex and require the attention of physicians trained in transplant medicine. However, the insurance industry often dictates the care of transplant recipients and may prevent patients from returning to a transplant center for medical management. This practice can lead to less than optimal care and, unfortunately, decreased survival rates. Furthermore, transplant centers are held accountable for the survival of their patients, even when they are prevented from delivering the appropriate care. Thus, the AST supports initiatives that guarantee long-term patient follow-up at the patients transplant center or an appropriate center within the patient's geographic region.

In an effort to protect the scarce resource of a donor organ, AST supports the following initiatives:

- Extension of coverage of immunosuppressive medications for the lifetime of the transplanted organ;
- Patient access to their transplant center;
- Access to insurance coverage, especially for pediatric patients; and
- Development of programs for patient and professionals education regarding early treatment of diseases that frequently leads to the need for organ transplants.

Education and Awareness – Patients & Physicians

The AST knows the education and awareness of patients and physicians alike is crucial to the delivery of effective health care. The Society has developed several educational programs to provide updated information on issues regarding organ failure and its complications, the transplant evaluation, and the transplant procedure itself. The organization has crafted a program devoted to the care and maintenance of a transplant after it has occurred. Through these efforts, the AST strives to minimize and eliminate any questions or confusion that may arise as a patient is considering this life

saving surgery before and after transplant. The Society is also actively involved in the education of physicians.

Specifically, we have a number of efforts directed at physicians not actively involved in transplant programs, but involved in the care of patients with organ failure, so a timely referral can be made to the local transplant center. The goal of these programs is to insure that all Americans have equal access to solid organ transplantation. The issue, Chairman Clay and members of the Committee are the unfortunate ignorance of those not familiar, both physicians and patients, with the criteria for transplant candidacy and outcomes. Our programs seek to address these gaps in education. That said, more needs to be done to educate the community.

In my own institution in Missouri, Dr. Amy Waterman, a social psychologist and Assistant Professor of Medicine in the Division of General Medical Sciences at Washington University, is conducting groundbreaking work examining increased patient awareness regarding kidney transplantation. Waterman is currently developing living kidney donation materials focusing on racial differences in attitudes about diabetes and organ donation. Part of her work is funded by the Health Resources & Services Administration (HRSA) through a grant looking at educating patients at kidney dialysis centers about the availability of kidney transplantation. The data obtained by Dr. Waterman and her colleagues will hopefully lay the groundwork for similar programs across America, as we continue to fight the battle against the misinformation and lack of information regarding this life saving therapy.

Outreach to Underserved Patient Populations

In an effort to reach patients in areas that remain underserved and not necessarily knowledgeable about transplantation, I have spent the last four years conducting patient outreach clinics in rural areas of my own home State of Missouri. Although my medical institution is based in St. Louis, many rural citizens across the State of Missouri are not able to travel to the city for education, evaluation, possible diagnosis, and treatment. To combat this situation, I and my colleagues have established clinics in underserved areas such as Cape Girardeau, MO. Cape Girardeau is a town approximately 120 miles southeast of St. Louis with a population of 70,000.

For various reasons, many of the town's citizens do not like to leave or travel to large urban settings and will refuse a referral to St. Louis or other large cities, in spite of a defined need. My presence and that of my colleagues has allowed these patients and their physicians to see the need for solid organ transplantation and simplified their need.

Addressing Disparities in Solid Organ Transplantation

In 2002, end stage renal diseases (ESRD) Medicare (CMS) program costs $17 billion or 6.7 percent of the overall budget. In the United States, ethnic minorities suffer disproportionately from kidney diseases. African Americans comprise 35 percent of the Medicare dialysis population. Compared to Caucasians, the incidence of ESRD in African Americans in 4-fold higher than that of Caucasian counterparts. This is also true for Native Americans among Zuni Indians in the American Southwest in whom renal

disease in 18-fold more prevalent than for Caucasians. Hispanic Americans have 2-fold the rate of ESRD of non-Hispanic Caucasians.

The excess burden of kidney disease in minority populations reflects, in part, the higher rate of known medical and environmental risk factors for ESRD and for other end-organ failure, including genetic predisposition, diet, lifestyle, Type II diabetes mellitus and hypertension and delays in receiving appropriate treatment. In the Native American dialysis population, 73 percent are diabetic and 83 percent are hypertensive. In African Americans, hypertension is prevalent and less well controlled by conventional medical therapies.

The Diversity and Minority Affairs Committee of the AST convened a symposium to examine organ transplantation in underserved and minority populations. The goals of the meeting included "benchmarking" of solid organ transplantation among minority populations, review of the epidemiology of the end-organ damage, exploration of barriers to transplantation services and development of approaches to eliminate disparities.

Participants in the symposium noted that minority populations were more likely to be adversely affected by limited preventive medical care, lack of counseling regarding transplant options, and delays in transplant referrals for organ transplantation. These features largely reflect economic disadvantage as well as the reduced presence of minority professionals with training in transplant-related specialties.

Participants in the conference noted that recent changes in organ allocation policies had improved access to minority individuals once listed for renal transplantation. Similar advances will be needed for other organs to address inequities in pre-transplant care and under-representation of minorities among transplant professionals. The biologic basis of differences in transplant outcomes for minority recipients has not been adequately studied. Research funds must be targeted to address biologic mechanisms underlying disparate transplant outcomes including the impacts of environment, education, poverty and lifestyle choices.

Removing Financial Disincentives – Family and Medical Leave Policies

In 1999 the AST and other transplant organizations worked closely with Congress to pass and enact legislation providing up to six weeks of paid leave for federal employees seeking to donate a life saving donor organ. Congressman Elijah Cummings of Maryland spearheaded this initiative in the House of Representatives.

In addition to federal leave laws, the AST initiated its own private campaign entitled the, "AST Employee Leave and Donation Program." The purpose of this campaign is for our transplant physician members to reach out to corporate American and encourage them to amend their employee leave policies to allow adequate time for employees to serve as a living donor. This effort has resulted in many company's changing their rules and removing a financial disincentive to donation.

Insurance Coverage, Immunosuppressive Medications – Preserving the Life of the Life Saving Organ

One of the greatest barriers at every stage of the organ transplantation process to many individuals is the lack of insurance coverage. This barrier exists from the time a prospective recipient is eligible for listing on the transplant wait list and persist after the transplant itself. Once a recipient receives an organ transplant, the AST and its membership supports measures to ensure that the care for patients are optimized and that the transplanted organ will last as long as possible. To this end, a most important objective is the support of legislation providing coverage for immunosuppressive medication for the lifetime of the transplanted organ. To clarify, patients must take immunosuppressive anti-rejection medications for the life of their transplanted organ.

For many years, the federal government would pay for a transplant operation but only cover 36 months of transplant immunosuppressive drug medications. This was obviously a flawed policy that resulted in patients losing their transplanted organ, returning to dialysis in the case of kidney, or losing their life. From a pure cost perspective it also proves to be more expensive to return individuals to dialysis and/or re-transplant.

As you know Mr. Chairman, last month Congressmen Dave Camp (R-MI) introduced a bipartisan measure, H.R. 3282 to cover gaps in Medicare program coverage for immunosuppressive drugs. The legislation, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2007", supported by you and other members of the Subcommittee, would be a solid step forward toward ensuring that transplant patients remain healthy.

The AST supports initiatives that ensure the coverage of immunosuppressive medications for the lifetime of a transplanted organ, regardless of age and ability to pay. Ultimately, this will lead to improved transplant success rates and the greater ability of transplanted recipients to return to a normal life.

Mr. Chairman, Ranking Member, and Members of the Subcommittee, the AST thanks you for the opportunity to participate in today's forum. We applaud and commend your leadership and efforts on this important issue.

The "gift-of-life" though often surrounded by tragic circumstances, can prolong the lives of affected Americans, allowing them to maintain their roles as active and productive citizens of our great nation.

Mr. CLAY. I thank you very much, Dr. Crippin. Thank you for the endorsement of the legislation.

Ms. Rubin, you will be the final witness of this panel, and then we will get to the question period. Please proceed.

STATEMENT OF ELIZABETH M.P. RUBIN

Ms. RUBIN. Good afternoon. Thank you very much for allowing me to speak today. My name is Elizabeth Rubin, and I am here to represent transplant recipients and patient advocacy groups.

As Chairman Clay already reported, I had a liver transplant 15 years ago. At the time, I had a very young family—a 4 year old daughter and a newborn. I took my good health for granted, and when I suddenly learned that my liver was not functioning properly I did not take it seriously. I chose to ignore the symptoms of lethargy and nausea to continue with my daily activities. After my gastroenterologist had done all the testing he could, coming up with no clear diagnosis, the test for hepatitis and other known liver diseases came back negative. He called my husband and told him, "You need to get her to a hospital that can handle this, like the University of Pittsburgh, immediately."

So we did, complete with little children in tow, much to the chagrin of my in-laws, and within 5 days I was listed for a liver transplant, entering into that cavern of the unknown, because in those days there wasn't much published information on what to expect while waiting for or going through a transplant.

This was the picture that sold my story, the one the doctors used to argue MetLife Benefit to get me on the transplant waiting list. I spent close to 5 months in Pittsburgh for them in and out of the hospital under the watchful eyes of Dr. Starsal and his protegee John Fung, and spent the remainder of the time trying to get my body to accept the foreign organ.

The diagnosis that I was finally given for my liver failure was Cryptogenic Cirrhosis, which had no cause and therefore should not repeat itself in my system.

There were some complications along the way, and it was not until my 4th year post-transplant that things started to level off and I could finally return to my life, my new, normal life.

Talk about a lesson in mortality.

The increase in the number of patients on the transplant waiting list is both a positive and negative sign of what has occurred in the transplant world—positive because improvements in medical technology have made it possible for more patients to be listed for transplant, but negative because the number of donors has not increased at the same pace as the number of candidates.

It is imperative that we come up with recommendations on how to increase the number of donors to regulate this country's organ and tissue donor system so that no transplant candidate will be turned away, forced to die rather than to celebrate a second chance at life, as I have been so fortunate to be able to do.

In preparing my testimony today, I consulted with several of my transplant friends to get their input. As a member of the Board of TRIO, serving in many positions, including President of the Board, as well as a transplant recipient, myself, I feel as though I represent the heart of the transplant community. TRIO's mission is to

improve the quality of lives touched by the miracle of transplantation through support, advocacy, education, and awareness. As a non-profit, international organization, TRIO has been in existence for over 20 years. Many of our members are transplant recipients. We are proof that transplantation works.

You can read more about what TRIO has done to improve the awareness of the need for donors in my full testimony.

The efforts of TRIO members and other patient advocacy groups over the past decade have improved the rate of donation, but not enough. There are five areas in which I recommend we concentrate our efforts in tackling the donor shortage.

First of all, for anatomical donors, we should continue to expand the criteria for viable donation. Research should be continued to determine what other categories of potential donors may be acceptable. This may include the use of extended donors and cardiac death patients. I would also suggest that we support and promote stem cell research.

Second, we need to push for a standardization of State registries in all States of this country. It has already been proven that the number of donors has increased in States where registries exist, but not all States have passed laws that favor donor registries. Perhaps in addition to drivers license centers, people should be given the option to sign up on line, as well. Nationwide practice of this and a national data base would allow OPOs throughout the country to access the donor list no matter where a potential donor was at the time he was declared brain dead.

In addition, regulations need to be standardized and regulated across the United States with regard to the integration of organ donation responsibilities among hospital staff, OPOs, and State registries. The Organ Donation Breakthrough Collaborative has already proven that this will increase the percentage of organ donors, but this collaborative needs to be extended to all hospitals, OPOs, and State registries in the United States.

Another recommendation is that we seriously examine the possibility of presumed consent as a law of the land. If an examination of the data available from countries using this approach indicates that this could be feasible in the United States, we could then enlist technology to allow for online opting out or allow people to go to State registry locations to physically opt out.

If presumed consent is not deemed feasible, then we should dedicate some time and resources to finding acceptable methods of offering incentives to people who are considering signing up to be organ donors.

My final recommendation for deceased donors at this time is that more effort and funding be put into educating the public on the need and reasonableness of organ donation. Organizations such as TRIO that are successful at doing this should be awarded grants to continue and expand their programs.

Two areas where I can see expansion of donor awareness education are driver's education courses and Web sites on the Internet. Websites are an excellent example of technology's use to provide public access to a wealth of information and reports for patients and the general public.

For living donors, I also have a few recommendations.

Among the new programs aimed at increasing the use of living donors has been the establishment, as previously stated, by some OPTM members of directed donation programs. List and pair programs should be universally accepted at all transplant centers. Regulations need to be established and followed, thus removing the question of preferential treatment.

Another suggestion for living donors is to offer each and every one of them health and life insurance policies and long-term care and followup post donation. Even though transplant surgery has become less risky, living organ donation still requires one to go through unnecessary surgery, which may cause problems during or after surgery.

I have one more recommendation which, although it may not directly impact the number of donors, does impact the longevity of the lives of transplant recipients. It is crucial that we push through the bill promoting lifetime immunosuppressive coverage that has been sitting in Congress for years.

It is economically short-sighted to be pushing for improvements in the U.S. organ donor program if we do not concern ourselves with the fact that transplant recipients who cannot afford to pay for their transplant medications once their coverage runs out are dying. If they don't die, they may be fortunate to receive a second transplant, which is just stupid when there is already such a shortage of organs.

In closing, I would like to thank this committee once again for holding this hearing to discuss the potential opportunities for strengthening and improving our Nation's organ donor programs. I am honored to have been invited, and I hope that some of my recommendations will be considered. I also hope that discussions such as these will continue so that those of us living in the world of transplantation can help to continually update and improve the procedures and regulations by which transplant candidates live or die.

Finally, I hope that everyone in this room who is attending this hearing has signed up to be an organ donor and has passed this information on to all their family and friends and anyone else they know.

Thank you very much.

[The prepared statement of Ms. Rubin follows:]

Testimony

Of Elizabeth M.P. Rubin

Before the Information Policy, Census and National Archives Subcommittee

Of the House of Representatives on Oversight and Government Reform Committee

September 25, 2007

Good afternoon. My name is Elizabeth Rubin and I am here to represent transplant recipients and patient advocacy groups. To start out, I just want to tell you how glad I am to be here, or for that matter, anywhere! Were it not for the miracle of transplantation, I would have gone to the "Great Beyond" over 15 years ago, at the age of 36 years old. Up until the time I learned that my liver was failing and that I would need a liver transplant, I thought I was in tip-top shape, enjoying life to its fullest and taking my good health for granted. And, even after I had been informed that I was ill, I ignored the diagnosis and continued to pursue all of the activities that were part of my life at that time. I had just had a second daughter, and I had a four year old as well. My husband and I lived a comfortable life in the suburbs of Philadelphia, where he was employed as a business manager for an oil company, and I was working part-time as a legal assistant for a major law firm in the city. When my gastroenterologist gave me what he could of a diagnosis – he couldn't really determine what exactly was wrong because all of the tests for hepatitis and known liver diseases came back negative – I did not take it seriously; in fact, I denied it, and continued to swim 100 laps every day, and, as I said, do everything else as usual. Finally, my gastroenterologist had to call my husband and tell him just how seriously ill I was, adding, "you need to get her to a hospital that can handle this, like Pittsburgh, immediately". So, we did, and within five days, I was listed for a liver transplant, entering into that cavern of the unknown, because in those days, there wasn't that much published information on what to expect while waiting or going through a transplant. I spent close to five months in Pittsburgh, four of them in and out of the hospital, waiting a total of seven weeks for a transplant and spending the remainder of the time trying to get my body to accept the foreign organ.

A lot has changed since then. Fifteen years ago, there were not very many hospitals that did transplants, and the surgery was still considered to be risky. The results were quite depressing to look at: although the percentages varied depending on the organ transplanted, many patients did not even survive the first year, and the percentage of those surviving five years was not much more. Some patients didn't make it because the original disease they had attacked their transplanted organ; others were not as good at following their post-transplant instructions; and still others could not reach the point where their immune systems accepted the 'foreign' organ. Immunosuppressive drugs were still in their infancy: the options were cyclosporine and Prograf, or FK506, as it was first called, which was still in experimental form (not approved by the FDA). In fact, those patients who were given the latter were the test cases. As I went through the transplant process, I felt a little like an explorer breaking new grounds: I ignored the statistics, and decided that if I followed doctors' orders and took charge of my

life, I would be able to break all of the records and live a long life, despite this hiccup. After all, the diagnosis that I was finally given for my liver failure was Cryptogenic Cirrhosis, which had no real cause and therefore should not repeat itself in my system. But there were some complications along the way, and it was not until my fourth year post-transplant that things started to level off and I could finally rest a little easier. Talk about a lesson in mortality!

When I was listed for transplant, there were approximately 30,000 patients on the transplant waiting list; now there are over 97,292. [UNOS as of 9/24/07] This is both a positive and a negative sign of what has occurred in the transplant world: positive, because improvements in medical technology have made it possible for more patients to be listed for transplant, but negative because the number of donors has not increased at the same pace as the number of candidates. What has been done to encourage people to donate has been quite successful: for example, the increase in donor awareness and education activities has publicized the subject of organ and tissue donation, and we can assume that it has helped convince people to sign up to be organ and tissue donors. I am a firm believer in the power of speech, and like many other transplant recipients, I spend a lot of time telling people about my transplant experience and explaining why they should seriously consider signing up to be organ donors. Other efforts to increase the number of donors include the broadening of regulations allowing individuals to become donors, the development of state registries at such places as drivers license centers, and the establishment of living donor programs. But none of these efforts have done enough: the number of organ donors is not keeping pace with the number of patients on the waiting list.

This is the topic for discussion at this oversight hearing before the Subcommittee on Information Policy, Census, and National Archives. Although it is important to review what has been done to strengthen organ donor programs, it is crucial for us to spend our time today discussing what can and must still be done to improve the system. I am honored to have been asked to appear before you. As a member of the Board of Directors of TRIO (Transplant Recipients international Organization), including past president, and as a transplant recipient myself, I feel as though I represent the heart of the transplant community. For those of you not familiar with TRIO, we are a non-profit international organization committed to improving the quality of lives touched by the miracle of transplantation through support, advocacy, education and awareness. TRIO has been in existence for over twenty years. Our goal is to help individuals who are suddenly thrust into the world of transplantation, as patients, potential donors, and/or friends or family of patients or donors, so that they may learn to navigate the system and subsequently work with others to advocate for the rights of the transplant patient. Although some of our members are candidates for transplant or newly transplanted, many are individuals who have been 'out' for an extended period of time. We are proof that "Transplantation Works"! Some of our members have had their transplants for over 15 years, and they are still living quality lives. Most of our members come to us through our website or through word of mouth, although we do speak to patients in waiting rooms and put brochures in medical offices and other locations where potential members may appear. Our members do a lot of grass roots work, getting out the word of organ donation into their home territories and into their larger communities as well. Some of them work with their OPO's, and many of them work within local TRIO chapters organizing educational seminars, donor celebrations – both living

and anatomical -, and participate in athletic events such as the U.S. and International Transplant Games. All of these activities raise awareness of the success of transplantation and the need for more organ and tissue donors. In addition, some of our members have gone beyond their communities to join UNOS patient committees, and one of our members is currently serving on the Transplant Roundtable. We are constantly looking for opportunities to spread the word of organ donation and to improve the public face of transplant. We know how important it is to present a positive and accurate story on transplantation: what is presented in the media definitely has an impact on the decision to donate or not. TRIO has recently taken on the task of monitoring media presentations on the subject of organ and tissue donation in advertising, film and TV production by joining a group called Donate Life Hollywood. The efforts of TRIO members and other patient advocacy groups over the past decade have improved the rate of donation. However, they have not done enough to stem the shortage. The increase in the OPTN waiting list of transplant candidates far exceeds the increase in donor numbers every year. We are at a crossroads in the world of transplantation: the technology exists to make it possible for many illnesses to be treated by a transplant, and technology has also made the decision to donate and the carrying out of those wishes simple and straight forward.

The following are my suggestions for how we should tackle the organ donor shortage. For anatomical donors, there are five areas in which I recommend we concentrate our efforts. First of all, we should continue to expand the criteria for viable donation. We have already expanded the age range – when I was transplanted, the cut-off age was 70 – but we also need to continue the research necessary to determine what other categories of potential donors may be acceptable. Perhaps we should push for the use of "extended donors" and cardiac death to be totally accepted.

Secondly, we should push for individual registration with state registries in all states of this country. It has already been proven that the number of donors has increased in the states where registries exist, but not all states have passed laws in favor of these registries. This should become a nationwide practice and maybe there should even be a national database so that when you are traveling all OPOs in the country could know your wishes even outside of your home state where today you might be registered (today, only the region's OPO can access their own state registry if it is even in place). Furthermore, I recommend that individual registries override family objections to donation, that they be considered legal contracts, just like voter registration.

In addition, regulations need to be standardized across the United States with regard to the integration of organ donation responsibilities among hospital staff, OPOs and state registries so that viable organs are not wasted and organ procurement outcomes improve. The Organ Donation Breakthrough Collaborative has already proven that this will increase the percentage of organ donors. As stated in the Memorandum prepared for this Hearing, "During the program's first year, the 95 hospitals participating in the Collaborative achieved a 14.1% increase in donation, as compared to an 8.3% increase in donation at non-Collaborative hospitals." [page 4]

Another recommendation is that we seriously examine the possibility of Presumed Consent as a law of the land. Today there are enough countries using this approach to provide the data to determine whether this would be feasible in the U.S. If it is deemed possible, then there would be a need to enlist technology to allow for online opting out using a national data base as the security to assure people that

their organs would not be taken if they did not want them donated. If Presumed Consent is not deemed feasible in this country, then we should dedicate some time and funding to finding acceptable methods of offering incentives to people who are considering signing up to be organ donors.

Finally, I suggest that more effort and funding be put into educating the public on the need and reasonableness of organ donation, perhaps even rewarding organizations that do this, with grant money and formal acknowledgement of their efforts. We have already seen the Internet as a major force for general education. The UNOS web site as it is continually evolving is an excellent example of technology's use to provide public access to a wealth of information and reports that both patients and the general public need to make such decisions about donation and in choosing health care providers for transplantation. In addition, education in the form of 'advertising' is evident in today's grass roots initiatives driven by desperate families using websites and billboards to seek a donation of organs to save their loved ones' lives, but we could eliminate the controversy of individuals doing that and make it a full public press to benefit all patients, leveling the playing field as today's UNOS registry process does already in the area of listing patients.

For living donors, I have a few recommendations. In cases where living donation is possible, usually involving kidneys and partial livers, such donations are considered to be preferable to deceased donor organs due to the viability of the organ being donated. In many cases, these donor organs come from relatives who are more likely to be biologically compatible to the recipients. Occasionally, a relative comes forward who is willing to donate but is incompatible with the transplant candidate. Among new programs aimed at increasing the use of living organs to decrease the organ shortage, some OPTN members have established directed donation programs for the donation of kidneys in these circumstances. There are two such directed donation programs now: the "list" or "paired" programs. These two programs have been found to be quite successful in that they make use of more offered and therefore available organs. In the "list" program, a willing kidney donor who is incompatible with the transplant candidate he had intended to donate to will donate to another candidate from the waiting list with whom he is compatible. Meanwhile, his intended recipient will then be granted priority on the waiting list when a kidney that is compatible becomes available. In the "paired" program, two living donors deemed incompatible with their intended beneficiaries will be matched up with patients in which both donors are compatible, thereby providing each patient with a new organ. These two programs should be universally accepted at all transplant centers; regulations should be established and followed, thus removing the question of preferential treatment.

Another suggestion for living donors is to offer each and every one of them a certain amount of health and life insurance. I would also recommend that, as part of the follow-up, living donors be treated to long-term care. Even though transplant surgery has become less risky, signing up to be a living donor still requires one to go through unnecessary surgery, which may cause problems during or after the surgery.

I would like to add one more recommendation, which, although it may not directly impact upon the number of organ donors, would impact upon the longevity of the lives of transplant recipients. For years, we have been advocating for lifetime immunosuppressive coverage. It is time to push through the bill promoting this in Congress! It is economically short-sighted to be pushing for improvements in

the U.S. organ donor program, if we are not also concerned with the fact that transplant recipients are dying because they cannot afford to pay for their transplant medications once their 18/36 month coverage runs out. If they don't die, they may be fortunate to receive a second transplant, which is also stupid when there is already such a shortage of organs.

I congratulate this committee for scheduling this hearing to discuss potential opportunities to strengthen and improve our nation's organ donor programs and awareness activities. I am honored to have been invited, and I hope that some of my recommendations will be considered. I hope that discussions such as these will continue, so that those of us living in the world of transplantation can help to continually update and improve the procedures and regulations by which transplant candidates live or die.

Finally, I hope all of those involved with this hearing will sign up to become organ donors if you have not already done so, and tell your family!

Thank you.

Mr. CLAY. Thank you so much, Ms. Rubin.

Let me thank the entire panel for their expert testimony.

Since you have had the last word as part of the panel, I am going to let you start off with the questioning. Ms. Rubin, I understand you moved to the Pittsburgh area temporarily in order to have your transplant done at the University of Pittsburgh Medical Center. I am wondering if you feel having to move, albeit temporarily, was a significant disruption to you and your family's quality of life? More specifically, do you feel there are enough transplant programs nationwide that are able to serve the population adequately?

Ms. RUBIN. Well, remember this was 15 years ago. If I were to need a transplant now, I think I probably would have stayed in Philadelphia, but at the time Pittsburgh was the best-known for treating unknown diseases that required transplant.

It was inconvenient for us to move to Pittsburgh; however, my husband's company was very understanding and we did get a lot of help from family and friends and people we met out there as far as finding a place to live and care for our children, etc.

Mr. CLAY. You know, your testimony also brought out the fact of availability. I know a few years back I read about some programs in several States that offered prisoners the opportunity to be organ donors. What are your thoughts about prisoners being allowed to be organ donors?

Ms. RUBIN. Well, I actually am in favor of it, speaking personally. I don't know that other members of TRIO or other patient advocacy groups would agree, but I am in favor of it. If a prisoner wishes to donate, I think is a wonderful way for them to give back. I think that it will be a hard thing to sell to the general public, and I think it is going to be hard for some potential recipients, some candidates, to accept an organ from a prisoner, because there are people who believe that they adopt certain physical and mental characteristics from their donor.

Mr. CLAY. But you would have accepted the organ?

Ms. RUBIN. I would have accepted. I mean, we were getting to the point where Pittsburgh was doing research on pigs and we would have accepted that, too.

Mr. CLAY. I see. Well, thank you for that.

The next question is for both Drs. Crippin and Callender. It relates to cost analysis, cost of keeping a patient on dialysis versus the transplantation surgery and the cost of that, who those costs weigh out at the end. Go ahead, Dr. Callender. You can start.

Dr. CALLENDER. OK. Well, this was an issue that I looked at because it was clear that dialysis costs about $40,000 per patient per year, and many may not realize that the only place in this country where we have universal health is actually in end-stage renal disease, because we have Medicare and we have Medicaid, so well over 90 percent of patients that have end-stage renal disease actually have health coverage, so therefore we can get the data. The data does reflect that it costs about $40,000 per patient per year for dialysis, as contrasted with what you would pay for a transplant where you may have some cost in the first couple of years, but after the third year you are talking about break-even. That is why I made the comment.

Since most transplants would survive, based upon our studies over the half life, most of them would survive for more than 6 years. We are talking about a savings for each increased donor that you get of maybe $135,000 per donor because of the fact that it is only about $10,000 a year for taking care of a patient for a transplant after the third year, which means that every time you have a donor you have a positive situation. When you take somebody off of the dialysis list and get them transplanted, you have effectively saved the taxpayers and the Government a significant amount of money.

When we costed it out and looked at it, assuming that you saved $135,000 per organ and you then had that period of time, and if you are talking about just kidneys, alone, we figured it was about $236 million. But then if you looked at kidneys, if you looked at hearts, if you looked at deceased donors which could provide, for example, two kidneys, and a live donor one kidney, if you look at a deceased donor and you look at the heart, the liver, the pancreas, the small intestine, and you look at all of that, you can recognize that by transplantation and donation, when spending money for donation efforts, that you would save the taxpayers, the Government, millions of dollars just for kidneys, alone, and then billions of dollars if we talk about deceased donors who gave, let's say, the 3.5 organs per donor that is the goal for the Breakthrough Collaborative.

Mr. CLAY. And not to sound awfully cold, hard stats, so to say, but our colleagues would want to know what are the costs and effects of a bill like ours.

Dr. Crippin.

Dr. CRIPPIN. Mr. Chairman, I was going to give it a slightly different spin, and it gets back to Ms. Rubin's comments about immunosuppression running out after 36 months and patients covered under Medicare. There is a study by Mark Schnetzler, a health economist at St. Louis University, who found that, in patients who lost their kidney transplant, the cost of maintaining them on immunosuppression on average was just over $13,000 a year.

But to lose that transplant and have to go back on dialysis, the cost of the first year back on dialysis was a staggering $130,000. So by maintaining immunosuppression, again, for the lifetime of the allograft, at least for kidney patients where you don't have to incur the dialysis expense, it is a huge savings to our country.

Mr. CLAY. And is it true that the insurance industry, and I guess our Government, has this 36 month time limit of coverage?

Dr. CRIPPIN. No, it is not. The private insurers don't operate that way. I mean, it is has been explained to me that when this program was started years ago there was only so much money the Government could expend toward the cost of immunosuppressive medications. There have been studies looking at what if we paid for those medicines for the lifetime. Of course, it works into the hundreds of billions of dollars.

Dr. CALLENDER. And when you talk about the Medicare payment, initially it was for 36 months, and after 36 months coverage would end. I have a number of patients who are now back on dialysis because they couldn't afford to pay anything after the 36 months.

That is the time period at which we are breaking even, so it is a disastrous situation where you have a situation which they both talked about, where after a period of time there is no payment for immunosuppressive medication.

Mr. CLAY. And the policy ought to be changed.

Dr. CALLENDER. Yes.

Mr. CLAY. Thank you for that.

Ms. Dunn, I would like to spend a little time on the areas of family notification procedures and presumed consent of donors. What are the procedures for tracking down next of kin in a situation where the potential donor did not indicate whether a gift was intended? And what role does the OPO community play in determining the accuracy and validity of a deceased donor's choice?

Ms. DUNN. Thank you. That is an in-depth question certainly, with many parts to it.

The process that is in place based on conditions and participation in the Medicare program is that all hospitals in the country are required to do death notifications when someone is near death or death has occurred, and those phone calls come in to the OPO. At that case, in the case of brain death the OPO physically sends someone to the hospital to make a determination on donor suitability from the chart, to huddle with the hospital team—the nurses and physicians—to determine that brain death has actually been declared or is imminent, and then at that point to talk with the family about their options for donation.

If the person is on the registry, it is at that point that we search the registry to see if they are on it. If they are not on the registry, then a skilled team of professionals who have been trained in family interactions and bereavement care interact with the next of kin that has been identified by the hospital. Most of the time someone is at the hospital or they are reachable by phone. That conversation then takes place about that death has occurred, what the options are for donation, and how long the process will take.

That is, in a nutshell, how the process goes. Does that answer the specifics to your question?

Mr. CLAY. It certainly does. I was just wondering what other steps could be taken to improve contact with family? I mean, sometimes it is probably perceived as pretty cold when your representative shows up.

Ms. DUNN. You know, it is really a very fine line. You know, it is crucial that we have a good partnership with the hospital staff, the nurses and physicians, because they are the ones that have been with the family since the time of admission through the event that has led up to the point of brain death. If we don't have that relationship with them, it is difficult for us to have a meaningful conversation with the family about their options.

The fine line that we walk is if we are there too early, quite frankly, the reputation that a lot of OPO colleagues have is that we are vultures when we are in the intensive care unit, and we don't want to create a conflict of interest by being there too prematurely, so it really is a fine line.

I think the short answer is to continue to develop really strong relationships with hospital systems so that we are there appropriately talking with the care providers.

Mr. CLAY. And according to your testimony, you do a lot as far as looking for live donors, as well as getting people to declare, I guess, on the back of their driver's licenses?

Ms. DUNN. Yes, with registry drives that really is. With 28 States now having active registries that are registries of consent, all our efforts are to drive people to the registry.

Mr. CLAY. Thank you so much for that.

Dr. Pruett, would you please explain for us how UNOS is funded by its members and the policymaking functions it derives through its OPTN charter? How much Federal funding does the OPTN receive annually?

Dr. PRUETT. Thank you. The majority of the UNOS budget and the OPTN budget comes through the registration fees of putting a person who is waiting for a transplantation on the waiting list. That constitutes the vast majority of the moneys of the $30 million budget that is required to run the allocation system in this country.

The amount of money that is coming through Federal funding was capped in the initial NOTA authorization back in 1984 at $2 million and has never exceeded that degree of dollars, so the burden of the cost of running the OPTN is basically on the patients and the centers which goes through.

With respect to the policymaking functions, through the charter and through the final rule, there are a variety of areas. The first and foremost policy area that we are supposed to have policy about is equitable organ allocation. The second one is to reduce the risk of transmission of diseases through transplantation to potential recipients. We are to address the issues of socio-economic disparities which occur through transplantation and try to minimize those, and then there are some issues related to policy. The Secretary recently came with the notion that the OPTNs should have policy pertaining to the performance of live organ donation in this country.

Those are the charger areas that we are to address, and a variety of functions come up as time goes on which we also do, but those are the core areas that we are to address.

Mr. CLAY. In general, what are the demographics of individuals who make organ donations, both living and anatomical donation? Do they tend to be better educated or economically advantaged?

Dr. PRUETT. The donors or the recipients? I'm sorry.

Mr. CLAY. The donors.

Dr. PRUETT. The people who donate tend to be, in a large part, like Mr. Walls—educated and motivated to do such. And the people who are disadvantaged in our society who do not feel much of the motivation have a hard time sometimes generating the goodness of their hearts to think that they need to donate back to the system. It is not that it doesn't occur, clearly. There are clearly wonderful people throughout the entire system. It is our job as an organization and as a community of transplantation to embrace the good values of what we as human beings can do for each other to try and make that work, but on the whole there are disparities.

Mr. CLAY. And, in general, the initial reaction of family members when that option is brought to them? What have you witnessed?

Dr. PRUETT. I usually don't witness much of the donation process. We try, obviously, to separate from the transplant surgeon's

side. But just being a physician in the hospital, I have certainly seen plenty of folks die, and certainly have seen people who have been requested, and the people who feel like they have been given a short shrift in that they have not been treated fairly are oftentimes quite angry at the time of death, and oftentimes the concept of donation is just not in their parlance.

Mr. CLAY. Thank you for that.

Dr. Burdick, finally, is there reliable data available on the number of organs that are available to the listed patient population each year but are never transplanted due to the inability of a transplant center to confirm a donor's intent in a timely fashion?

Dr. BURDICK. I am not aware of specific data on that score. I think that the implication that one can draw from comments you have already heard, that organ donation has clearly been affected in a very positive way by State registries which facilitate just the concern that you have expressed in that question. It is an indirect way of indicating that system could use more facility, and it shows the benefit of it when the registry is in place.

Mr. CLAY. Let me ask you to what extent would increasing our donor pool help close the gap between the number of patients on the waiting list and the number of transplantable organs that are recovered? I am assuming that it will never be a perfect one-to-one ratio.

Dr. BURDICK. We did 26,000 transplants last year, and we can show that if we were to achieve the national average of the Collaborative goals of 75 percent conversion rate, and rounding off to four organs per donor, we would move that to just over 35,000. That is our goal now for our Collaborative for this coming year, with 97,000 patients on the list.

There are patients who are added, there are patients who die waiting, as we have talked about, but we can definitely begin to really turn around deaths on the waiting list and eventually begin to show an annual decrease in the number of patients waiting for this life-saving therapy if we can reach that level. So we are 9,000 donors a year away from having that, and it is a doable proposition.

Mr. CLAY. Thank you so much for that response.

Representative Lynch.

Mr. LYNCH. Thank you, Mr. Chairman.

I just want to ask one question and one comment before I ask it. With regard to the prospect of cultivating the prison population as possible donors, I do have some knowledge in this area. I know that there are some Asian countries that are very aggressive, to put it mildly, very aggressive in cultivating their prison population for organ donation. Creepy is a good word. But I think it also lends a stigma that we do not want.

From my own family's experience, I can say that organ donation, once it is understood—I remember Dr. Jenkins from the Leahy Clinic in Massachusetts explaining to me that the liver grows back after 60 percent of it is cut out for donation, and I kept saying, go over that part again. I am an attorney and considered myself fairly educated at that point, but I really honestly believe that education can do a lot of good in this area.

I want to register my vote in opposition to looking at our prison population. I think that their incarceration and the appearance of coercion is just inescapable. As a civilized society, we do not want to go down that road.

As strong a supporter as I am of organ donation, I think we can do it with well-educated and freely involved. I have the greatest faith in the goodness of humanity, and I have seen it so many times. We see it again here with Ms. Rubin and all of you.

I think that is enough said. I don't think we want to go down that road.

Second, I was struck by, Ms. Dunn, the difference in the increase that you saw in the Colorado/Wyoming example was a 40 percent increase, while the United States generally experienced a 25 percent increase. That is statistically significant, I think, and I wanted to know if there are any, besides your wonderful work, approach. What is causing that? What is bringing the results that you see in terms of greater willingness to donate?

Ms. DUNN. Well, it is really directly attributable to the work of the Collaborative, and partnering with the donor hospitals as well as the transplant programs for shared accountability. If you have a better partnership with the nurse at the bedside and the intensivist and hospital administration, donation becomes part of the fabric of the hospital so that it is always in the forefront of someone's mind, not in lieu of saving lives, but when all is done, there is nothing more that can be done, when donation becomes a question, then families have been treated well by the hospital and they are more inclined to say yes.

Mr. LYNCH. Well, I would be remiss if I didn't say thank you to all of you for your wonderful work and your continuing involvement in this issue. Certainly, we have a great leader in the chairman. I am sure that he will stay on this. I will be there to help him.

Thank you. I yield back.

Mr. CLAY. Thank you so much, Mr. Lynch. We heard you loud and clear about the prisons.

Let me ask a panel-wide question, and anyone can tackle it as you see fit. An area where we have identified significant potential for improving donor/recipient outcomes is in the area of paired and list donations. We can just start at this end of the table. Can you describe some of the systems or networks in place that offer paired or list donation programs? And are these simply demonstration programs that need more study, or are they being implemented nationally? We will start on this end of the table and move down.

Dr. BURDICK. At present the active systems are mainly programs that have their own local activity. There are one or two other regional, I think you would say, systems that involve multiple centers, and I don't have really a lot of specific information about this.

There has been some very excellent statistical work done to determine to what level the existence of a national system for paired donation in settings in which it is not possible for a given donor to provide an organ to a given, chosen recipient, but rather could to some other in an exchange way. This could be extended to produce the possibility of hundreds more transplants per year.

This system is mathematically quite clear. It has not yet been put into practice, but the activity of the OPTN in this area has only

recently begun to be directed toward these things because of the issues that have been barring Federal activity as a contractor of HRSA. Now that we are in a position to be able to give the green light to working on that system, the process is going to be worked on and explored, and we think it is very promising.

Mr. CLAY. Thank you.

Dr. Pruett.

Dr. PRUETT. Yes. It is an area that we are very enthused about. It is a potential. I don't even know the number of people who would like to donate who can't because of blood groups or sensitization or whatever reasons.

The major concern for us on the OPTN side and the UNOS side is to keep our enthusiasm inside of the notion of patient safety in that we want to make sure that whatever systems that we embark on is that we are setting up a system that is safe for the people who do it, that the organs go to the intended way that they want it to be done, that they are fully informed, and that, in fact, we can do this in the best possible way that we can.

So we are sort of on both sides. We recognize the tremendous potential and are tremendously enthused about that potential, and at the other side, we are on the cautious side as to say, as Dr. Burdick said, we are just now getting into a large part of this business because of change in both perspective and law, and from the oversight side we are now just starting to get into the oversight of life organ donation as part of our mission, so that we are still working through our processes to set our priorities for patient safety and equitable allocation.

Mr. CLAY. Thank you.

Ms. Dunn.

Ms. DUNN. Certainly there are a handful of OPOs that are involved in coordinating the live donation or the paired exchange program. I would say there are probably some differences of philosophy within OPOs that if we really turn our attention to facilitating paired exchange programs that it takes our eye off the increase in deceased donor donations, so that is where we sit.

Mr. CLAY. I see. Thank you.

Anything to add?

[No response.]

Mr. CLAY. OK. Let me ask another panel-wide question. I would like to address some of the issues regarding living donation. We can begin with Dr. Burdick and proceed from there. When screening living donors, are there standards established by stakeholders for the medical and mental screening of potential donors? And are there adequate counseling or information services provided to potential living donors?

Dr. BURDICK. As Dr. Pruett mentioned, this has recently been put into the expectations for our contractor, to have criteria for membership, for appropriateness of a program to be able to do living donation, and the criteria for consent. In fact, these have recently been established as policy by the OPTN.

There have been extensive discussions about much of the rest of what you asked about—that is, how well the counseling is done, how it is done, and, in fact, this is also an element in the regulations for transplant programs now put out by CMS.

The level of detail that one needs to get to in terms of medical practice, which is not exactly what HRSA oversees, is something that is under very careful discussion by the community now, and there will be further actual specific policy from HRSA's contractor, the OPTN, on this topic shortly, I think.

Mr. CLAY. Thank you.

Dr. Pruett.

Dr. PRUETT. I would just reiterate that there are a number of different guidelines and recommendations which have been put out by international transplant societies about what constitutes the kind of workup which needs to be done. It is in our literature. What we are trying to do in terms of the OPTN is set some resource documents for our members that they can both have for making sure that they are complete in the way they do things, but, more importantly for the people who are entering into live donation, to understand what the purpose of what we are to do in this endeavor.

What we really want is to make sure it is as safe as it can be done, that people can have the optimal amount of information that they need to make a good decision, and then to make that decision. It may be not to donate. It may be to donate. But we want to make sure that they have the information that they can use to come up with a good decision.

Mr. CLAY. Thank you.

Ms. Dunn, any thoughts? Doctors. Ms. Rubin.

[No response.]

Mr. CLAY. OK. I will allow anyone who wants to make a closing statement, a brief one, you can have at it.

[No response.]

Mr. CLAY. I see we have no takers. I will conclude by saying thank you to this panel, as well as Mr. Walls. We think this will be the first in a series of hearings on this subject. I think that any national discuss on health care should include organ and tissue donation, as well as how we make the process more efficient.

I want to thank you all again for being here, and that concludes this hearing. Hearing adjourned.

[Whereupon, at 5:05 p.m., the subcommittee was adjourned.]