2014 RUTGERS HEALTH LAW SOCIETY SYMPOSIUM ON ORGAN DONATION

FOREWORD

On April 9, 2014, the Rutgers-Camden Health Law Society hosted a Symposium on organ donation. Speakers included Jennifer Walter, M.D., PhD, M.S., of the Children's Hospital of Philadelphia, Jan Weinstock, Esq., Vice President, Administration and General Counsel of Gift of Life Donor Program, and Christina Strong, Esq., Counsel for N.J. Sharing Network. For more information on organ donation please visit: http://www.organdonor.gov/index.html.

HEALTH LAW SOCIETY SYMPOSIUM ON ORGAN DONATION: APRIL 9, 2014

Brittany Verga: So good evening, my name is Brittany Verga and on behalf of the Health Law Society I would like to welcome everyone to the 2014 Health Law Symposium on organ donation. For those unfamiliar with our Health Law organization, we are a student group dedicated to raising visibility of health law issues at Rutgers. This is a really exciting time to get involved in the expanding field of health law by joining our organization, or by taking advantage of the number of classes we offer here at this school dealing with the subject matter we have medical bioethics, healthcare commodities, as well as the general healthcare class, Health Law class taught by Professor Rosenblatt and Professor Frankfurt.

So now turning our attention to tonight's topic, organ donation, I would like to thank the donor and recipient families who are with us tonight in attendance. I would also like to thank the members of our interdisciplinary panel for coming out to speak with us. We have Jan Weinstock, who is Vice President and General Counsel of the Gift of Life Program; Jennifer Walter, who is with the Children's Hospital of Philadelphia as an ethicist as well as a physician; Christina Strong, General Counsel for the New Jersey Sharing Network. We're going to start the program with anecdotes from our donor families and then we'll have our panel go from there. So once again, thank you for, everyone for coming out tonight and I hope you enjoy the program.

Jan Weinstock: Good afternoon everybody, I think I could speak for my colleagues safely and say that one of our objectives are that before you leave the room today, if you have not already designated yourself as a donor, that you give serious consideration to doing that and if you have any questions to reach out to any of the mixed speakers of the panel as well as our colleagues here at the table. And I would like to introduce one of our extraordinary volunteers, Tom Gano, who has dedicated hours and hours to helping other people and he has been on the road since 7 A.M. this morning educating, so Tom.

Tom Gano: So good afternoon, or evening, I'm not sure which it should be, but my name is Tom Gano. Our family's introduction to organ donation actually occurred almost twenty-seven years ago, so this is back in July of 1987. At that time we had two boys who were already in high school and a daughter getting ready to start high school and we were kind of looking forward to it—it actually would have been the first time since elementary school that they were all in the same school together at the same time. I want to pass around a picture of my son Curtis. Curtis was 16 years old, he had just completed tenth grade, did have his learners permit, and because he wasn't seventeen yet he didn't have his license, so his main mode of transportation to get around on his own was still his bicycle.

On July 6, 1987, Curtis left on his bike to go visit friends. Now he was gone about six hours when we had gotten a phone call; it was from one of Curtis' friends, and he had informed un that on the way back home, Curtis was attempting to cross Route 70 in Cherry Hill on the corner of Springdale Road on his bike when he was hit by a van. Now when we arrived at the accident scene we were informed that, although Curtis was unconscious, his only visible injuries appeared to be a broken left leg and a few scrapes and bruises.

But as they were loading him into an ambulance, local, an ambulance to take him to a local hospital, they were going to take him to Virtua, they discovered that he stopped breathing. So they rushed him to the Cooper Trauma Center here in Camden. There they discovered that from the fall, and he travelled some 40 feet overall through the air after being hit before landing, and that caused a swelling of the base of his brain that cut off the oxygen supply to his brain, so he was put on life support at that time.

But two days later we were told that through EEG. machine [electroencephalogram, a measure of brain activity] use they had determined that Curtis no longer had any brain wave activity. Anybody here ever have an EEG done? I know my daughter had that done when she was about eight years old because she was having problems with seizures. They put tape all over your head, put wires to a machine and literally it looks like a wig. Okay? If you're having some kind of abnormality there would be a little spikes in it. Well, Curtis had no brain wave activity, so what did his look like? It looked like a straight line, like you see on an EKG when the heart stops, it means the brain stopped.

That didn't mean he was brain dead; that meant that they now had to have two doctors come in and test him for brain death. And these two doctors do their testing some time apart. What these doctors are actually looking for is some type of body movement. Now if you were to have any type of body movement it means you have to have brain functionality, in order for that body movement to occur. So regardless of what the machinery would say, you can't be pronounced brain dead if you have any type of body movement. Now I watched both doctors perform those tests — they do pretty much the same testing today that they did twenty-seven years ago. The very first thing they are going to do is disconnect you from the ventilator you are on. If you took a breath on your own, that'd be considered body movement. That could back up that you're not brain dead. Then they are going to run a series of tests from head to toe, looking for some actual body movement and in lieu of that they will look for dilated movement of the eyes. And if your doctor couldn't find any such movement he would in fact declare.

Curtis was, in fact, brain dead. Curtis ended up being declared dead at 12:10 that day. That's on his death certificate, 12:10 that day. Curtis's heart was still beating. Your heart is a muscle. Your heart does not need brain activity to work. He was hooked up to the ventilator; he had oxygen flowing to his body, that's when he became a candidate to become an organ donor. And we were then put in contact with a transplant coordinator with the Gift of Life Organization.

Now she arrived sometime after one o'clock. She carefully explained all of the organs and tissue that could possibly be donated, and we ended up agreeing to donate all of Curtis's organs plus his eyes and his skin. So Curtis' heart and lungs ended up going to a 53-year-old man with two children, one of his kidneys went to a 44-year-old man with two children, the other to a 17-year-old boy. Now your pancreas and your liver are very close together. Twenty-seven years ago they actually had no way to successfully be able to separate and use both organs — you could only do one or the other. So they ended up transplanting Curtis's pancreas. That went to a 45-year-old man with three children, someone who never made it on as a person who'd suffered from juvenile diabetes his whole life, now at the age of 45 was diabetes free.

We did agree for his liver to be used for research. Now of course today not only can both organs be transplanted separately, it's also possible split the liver in two from the deceased. This isn't something that's done a lot today, but if it were to be done, a smaller portion usually goes to a baby and a larger portion to an adult. Now the case that I know about, a four-month-old baby girl at Children's Hospital received 25% of an adult liver, a baby can only use up to 25%. 75% went to woman that is over here in New Jersey. That process of splitting the pancreas successfully and being able to use both for transplantation, that process was actually perfected around six months after Curtis passed away. So we always felt that donating the liver for research helped to make that possible. It's probably not true, but it's something my wife and I like to think that.

So I talked about Curtis' eyes. Now, I'm going to talk about his cornea. Your cornea covers the whole outside of your eye, but the only part of your cornea that can be removed and transplanted is a little portion. It's really only about the size of a little smaller than what a contact lens would be. So both of the little portions of Curtis's corneas were removed and went to Wills Eye Hospital to help someone see.

I've also, I do a lot of school talks. I've been in schools, and I've actually met students who've had cornea transplants. The first one I ever met was an eleventh grader. He explained to us he had actually gone blind in both eyes before he was eight years old. He said at the age of eight he received a double cornea transplant now I have twenty-twenty vision in both eyes and can see perfectly well.

So I talked about skin, back then skin was only used for burn victims. Now the only skin they took from Curtis for that process came from like the back thigh area of the back. They explained to us that was the fatty area of your body, they only remove the top layers of skin. It's almost like, if you've ever had severe sunburn and you pull a couple layers of skin off, that's really about the thickness of skin they use for this process. Now they save that skin all for someone that has severe burns as soon as that area gets cleaned up, you take skin from the deceased donor and lay it over that area, but it's only there as a temporary cover to prevent infection until your own skin grows back. That process might have to be done four or five times until your old skin grows back. It's not skin grafting. A skin graft is something, you pack a layer on once the area starts to heal.

One of the questions I get most from the donor side is, "How does it affect your funeral if you're an organ donor?" Removing organs and tissue is an operation; they're going to close you up like any other operation. There is nothing to see. So you can always have an open casket viewing like we had with Curtis, unless you told someone what had been done, no one would be able to tell. I really do want you to go home tonight and talk to your family and friends about what you've learned here today. It's my hope that when the time comes, perhaps you may too give the gift of life, like my son Curtis was able to.

Brittany Verga: Could we have our recipient family come up here?

Audience Member 1: I'd assume you'd need no introduction, but you'll be introducing yourself.

Russ Jackson: Good afternoon everybody, my name's Russ Jackson. December 22, 2010, I received a heart. I stand before you a much better person. The procedure that I went through was nothing; the recovery was quick. My donor is a 44-year-old college professor. He had a brain aneurism. He was a hero. He was able to donate every organ to save a life plus enough skin cell, bones, so on for fifty additional people to enhance their lives.

I was lucky enough and fortunate enough to meet the donor family, which is an emotional roller coaster. We now have an extended family, unfortunately they live up in Rochester, New York, Enola, Pennsylvania, so it's a lot of traveling to meet them and see them. So we decided every year we would meet on December 24th at a diner in Freehold. It works out well because the sister-in-law lives in Toms River, and they come up every year for Christmas to see her parents and we kind of meet in the middle now.

Meeting them was probably the most emotional thing I went through in my life, and I was a cop for twenty years, so I've seen a lot of stuff. But I guess when it's personal, it's a big difference. I have to say right now I owe it all, most of it, to New Jersey Sharing Network. They're the people that coordinate everything so I can get my heart from Rochester, New York. It's a distance. I remember laying in bed, it was 2:00 in the morning, had five or six nurses come running into the room saying "Mr. Jackson, we've got a heart for you. Wake up, wake up!" I said, "What, are you going to put it in me right now? Let me sleep a little bit," cause I knew the process was going to be long.

But they wouldn't let me sleep, they wanted to prepare me. So I said okay, you've got to give me a couple minutes. First thing I did, what I do, I go on Facebook to let everyone in the world know they got a heart for me. Then I called my wife. It was in Beth Israel hospital and the neighborhood there is not that good so I explained to her, I said, "Listen it's going to be quite a few hours before they get me out the door, so take your time and come in the morning." So I guess about fifteen minutes later she's at the door. She couldn't wait. She slept there that night.

But the experience that I had personally, before I got the heart, I was literally on death's door. I got a regular presentation I normally do but it takes an hour so they said cut it. During that presentation I give to nurses and all at eastern colleges, and none of them know at the time that I'm a recipient of a heart; they just think I'm a regular volunteer for the Sharing Network. I got a certain section in there where I play the song "Knock, Knock, Knocking on Heaven's Door." Anyone ever hear that? It's a very sad song, but it covers my points. I was a cop, so take my badge away, bury my guns, and so on and so forth. It's actually how I felt at the time. But once again, I gotta go back.

I've done a lot of stuff with the New Jersey Sharing Network. I met a lot of nice people. I'm based up by Mets stadium, that's where I work, so we drove down here today. That's how important it is to us, that everybody becomes a donor and helps somebody out because some day you might need something. I never looked at it that way before, but the shoe can always go on the other foot. What I can say right now is I'm alive because somebody donated to me. And there's actually another 58 people that are alive today because of one donor. It doesn't always work that way, but in my case it worked and I'm very happy, and I thank you for all your time. Thank you.

Christina Strong: So you've heard the important part of the presentation. Anything else is just legal background. You're law students though, I thought you might be interested in the legal background, and there's plenty to talk about. I'm the general counsel for the New Jersey Organ and Tissue Sharing Network, which is an organ procurement organization, or OPO, and we're going to talk about what that is and what role it plays. I'm a healthcare attorney. I'm a Rutgers Law grad, 1988 Newark, and I do other things beside organ donation, but a concentration of my practice is in fact in this area.

And these are the statistics that bring us here, you see the people who bring us here, but there are nationally over 117,000 people waiting for a transplant. There are over 4,700 people waiting for a transplant in New Jersey alone. I prepared this PowerPoint six months ago, all these numbers are different. All these numbers are higher, and I can say that with great confidence. All of us, as we go around the country talking about this issue have been using this one statistic if it sounds familiar to you, that every day, eighteen people die while waiting for a transplant. And we played with these statistics to see what they actually mean. And then I finally took a look at the data that was prepared by UNOS [United Network on Organ Sharing], they gave us that eighteen person a day number. And eighteen people a day is a 747 going down every month, so that you get a picture of the nature and the amount of the crisis.

When I really looked at that data and a colleague of mine talked to the data people, it turns out that those are the people who die while they're on the waiting list for a transplant. It doesn't include the numbers of people who were on the list and were taken off because they got too sick to be able to benefit from this therapy, and they got too sick because they waited so long. So when we rejiggered the numbers it turns out we're losing two 747s a month worth of people for want of an organ. And that also means that as that list is growing, the list of people waiting is also growing because organ transplantation is a successful therapy and many of the people who need that therapy cannot be saved by any other therapy so the waiting list for transplants is growing incrementally and in increasing numbers every year.

So what? Compared to cancer rates, that is very, very small. So why would a Rutgers Law grad devote much of her career to this issue if you're trying to max out whatever kind of knowledge you've gathered and your desire to do good, why would you focus on this particular issue which in the greater scope of public health is not the one killing the most people? Well, compared to our known improvement and ability to treat, this is a very interesting question because we know how to treat the illnesses that are cured with organ transplants and there's very finite reasons why this is not happening to the extent that it could. So it's very easy for a simple person such as myself to get their arms around the need for organ donation and to try to figure out how to increase it because increasing donation will go very far to actually saving those airliners. And when you think of how much work we have put into finding, even when it's probably passed all hope of saving, our most recent airliner, you can see how this has a pressing feeling. Why aren't we talking about this as much as we could be?

So the reasons for our inability are complex, frustrating, they have a lot to do with the system, which I think is very much like our judicial system. Just because you can see the problems, it's very hard to come up with a viable alternative for doing it better but that's one of the things we're all going to be talking about today. But at the core the causes for the lack of organs for transplant are very human.

Just so that we know what we're talking about for today, we're primarily going to be talking about the organs one can recover from a deceased human for a transplant. Some of these organs you can also, as we've heard, recover from a living human being, part of the liver, kidneys, and that will not be a primary focus of the systems that we're talking about today. The ability to transplant organs goes back a ways and the law followed along with the development in our ability to transplant pretty much apace in fits and starts. This was one of the first successful kidney transplants, and you can maybe guess why it was successful. There was no issue of rejection here because these were twin brothers. The donor lived for fifty-six more years. I think the recipient lived for five, which was significant back for 1954. Now our survival rates are much, much longer, and we don't actually set limits on them.

In order to do and recover organs for transplant early on, it was a little difficult because we did not have a definition of death that encompassed the ability to recover from a brain dead individual. So organs to be transplanted needed to be profused with oxygen, and for that to happen, a person has to be on the ventilator. As we've heard, that can go on for days, keeping organs transplantable. But when someone is on a ventilator, their heart is still beating. If the legal definition of death only encompasses the idea of you're dead when your heart stops then, if you follow the legal tautology, you're recovering an organ from a live person, and that's a problem under our system, actually all around the world, when it's organs like a heart, that a living person can't donate. So we needed to have a statute that would encompass the idea of brain death, which is the process that Tony described so well, when the brainstem has died and it is an irreversible condition. And that only started to become definitively set forth in statutes in the 1980s, with the Uniform Declaration of Death Act and through some of the Harvard Medical School work, and the President's Commission on Bioethics. That's a subject entirely another topic in and of itself.

So we're talking now somewhere between the fifties and the eighties, we're starting to realize that deceased human bodies have great value to sick living people. What do we do with that issue legally? How do we fit that into a structure when prior to that window of time the only issue surrounding deceased human bodies were their dignity and were their use for medical school cadavers or practice for medical schools? So in the early eighties as we're starting to realize the transplant value of organs, Congress moved to create the National Organ Transplant Act. And that created an entire system of organs for transplants in a way that based, as its core, the fact that organs were a national resource and that organs could not be bought or sold; that they were not to be a marketable commodity. That alone is a core legal judgment that did not exist before. And it came about based on a framework and that's federal law, and it's federal law that remains today, based on a state law concept of the Uniform Anatomical Gift Act, which also created a framework saying that organs could not be bought and sold within the states that adopted that act, and that organs, when they were to be transferred, would be transferred subject to a gift.

This National Organ Transplant Act created a number of things but among them are organ procurement organizations, which is what the New Jersey Sharing Network is, which is what Gift of Life out of Philadelphia is. It divided the country into something called donation service areas, and you're looking at them right there, and each donation service area has an organ procurement organization. That organ procurement organization is tasked with recovering the organs from every acute care hospital within the geographic area. So a fact that the public is often not aware of, and which maybe only comes as a surprise to lawyers and law students and our field is that every single death that occurs at a hospital is phoned in to an OPO. We don't ask your consent. We exchange personally identifiable information with every death and every imminent death because OPOs need to be able to work quickly and that's one thing that the media when it's covering organ donation gets right. There really are people running down the halls with coolers. It really is a process that once an organ is recovered has to move fairly quickly and given our death rates, that's the other reason it has to move fairly quickly. So we get this information on patients very, very early at the organ procurement organization, and it all derives from this federally based system. In New Jersey, the two OPOs are the Sharing Network, which covers roughly the northern three quarters of the state, and the Gift of Life, which covers this service area except for some of the hospitals within. And hospitals can choose which organ procurement network they choose to work with.

So these OPOs are tasked with creating donation, and some of the rest of our talk is going to be about once we've recovered these organs how do we share them, how do we keep it fair, how does the system work, how do we run our waiting list. But none of those questions can be answered until we actually have organs donated that we can have a case. So I'm hoping to kind of create the foundation for the rest of the discussion by talking about how do we get these organs that we're later fighting about in the first place.

So as health law students we know that a lot of the healthcare decision making statutes, because of the constitutional structure, are created on the state level. So what do we do when we have state laws, and states having the ability under the Constitution to make laws, which nevertheless need to be fairly consistent nationally? Well there's a committee, kind of a fourth or fifth estate called the Uniform Law Commissioners, a national council of commissioners on uniform state laws. They're the folks who brought you contract law and the UCC. There's many, many uniform statutes and among them is the Uniform Anatomical Gift Act, which they draft as a model and then the states are free to adopt.

In the case of the Uniform Anatomical Gift Act, it was the most quickly written act in the United States ever. It was drafted in 1968, and it was drafted because we started to see people selling their kidneys in a public forum. And we realized we've got some decisions to make here legally. What is the status of a deceased human body? Who owns it, who can make decisions in that regard? Every state adopted this initial Uniform Anatomical Gift Act back in 1968 within a year and a half, which is an all-time record. The UCC took about five or six years, and that was pretty needed too — you know what a contract is. So that kind of gives you an idea of the way the importance was looked at as these technologies were growing. Other areas that state law controls when it comes to uniform gifting and to the ability to donate and reach human organs are hospital licensing regulations because all organs for transplants arise from hospitals that can put people on a vent. Tissues can arise from other health care facilities, but organs all come from the hospitals.

We also have to look at state law on how we dispose of bodies. Who has control over the disposition of a deceased human body in the family? Right now if you think about it, none of us think about ourselves because we in this room will never die, but I've heard of other people who do. Who's going to make the decision about whether there is cremation or burial? Who has the right to make that decision? Who has the right to make the decision if you are going to be a donor or not if you haven't exercised that right yourself? So we look to state law to answer those questions. And who else cares about deceased bodies other than people on the waiting list, is coroners, because they want to know how you got there. And your body is primary evidence that a crime may have been committed or that there is a huge public epidemic of disease *X* that has heretofore gone undiagnosed that the coroner can catch. So there is a state law way of dealing with the kind of differentiation between a deceased human body as being the source of organs for transplant, and being the body of my mom whom I love and I want to bury properly, or as being the source of evidence of a potential crime. And of course over all of this as sources of state law is the common law, and the way courts have interpreted, occasionally in a vacuum, how all of these rights work.

We also have something that I will roughly refer to as contract. You should know that Medicare requires every hospital to have an affiliation agreement with its OPO. And there are terms within that agreement as to how hospitals and OPOs work together. Those terms are mandated by the federal government for the most part, and they have been a huge blessing, a sea change. Jen and I both go in this world together a ways back, and there were times when we would had a family that wanted to make that gift and a hospital who would say we are not going to give the medical record because it's private. We are not going to let you assess the donor because we have to follow laws. And these affiliation agreements that we're mandated to have give everyone protection to collaborate and work effectively to make donation happen.

The last thing that I am calling a contract, but that's way too loose, this is a slide deck created for lay people. But when I sign a document of gift, it is a testamentary gift, and I am saying what I want to have happen to my body after death, if at all possible. And I am saying, and have the ability to say under statute, what I don't want to have happen. So if I don't want you to use my body for research or in the medical lab, I have the ability to say that. And the people in charge of facilitating my postmortem wishes need to be able to adhere to that. And state law furthers that agreement in that contract between me, the now living, making my wishes for postmortem known, and whoever is there after I am gone and no longer able to enforce my own wishes.

The other thing that this Uniform Anatomical Gift Act had to deal with which was, what is the gift? What is this thing that we are doing when we are quote unquote "donating our body?" The recovery of organs, as we heard, is surgery. So is this informed consent for surgery? But we've always looked at bodies after death as being property or quasi-property, is something one law professor calls quasi-property, which is a concept that is only going to fool a lawyer, because we know that bodies aren't really property. What we are protecting when we protect the dignity of a body is the feelings of family members about that body. Because while that feeling may be irrational and difficult to quantify under the law, it is real and it is universal that people have feelings towards the remains of their loved ones that need to be protected and respected under the law. So the statute attempts to deal with this by making clear that this is not a medical consent. And as you will remember, medical consent involves identifying to the consenting person what the risk is of what they're doing, what the benefit is of what they are doing, what the alternatives are to what they are doing. None of that fits when I make the decision to be an organ donor. Because one thing we know about dead people is they are beyond risk and they are beyond benefit, and there are no alternatives when they get there, unless you believe in some, which we are able to protect as well. So this is not an informed consent decision you're when you are signing up to be a donor. It is not an informed consent decision that your family is making. It is much more like a charitable gift, which is why we call it the anatomical gift.

And what do you have to know or do under the law to make a gift? You have to know roughly or broadly who you are giving the gift to. You have to know what the purpose is. You have to know how it's going to impact you. And you have to know that you are not getting anything back for that gift. That's what makes it a gift as its core. And so that's what the Anatomical Gift Act requires for people to know before they sign up to be a donor, either of their own bodies or the bodies of their loved ones.

So the other things that the anatomical gift answers, which are pretty key to any kind of a testamentary gift, a gift that you make while alive to take place after you die, is how to document that gift, how to take that gift back. And in this process in particular, again which takes place in hospitals, with doctors, and quickly, and involves human feelings, we need to have a certain protection from liability for people participating in it. Because if people don't participate, we're going to lose more of those thirty-six lives. And to the extent that they do participate, we're going to gain some more lives.

So the way the law in general answers these questions, and I think this is true in both New Jersey and Pennsylvania, is that to give this gift you have to be over eighteen, you have to sign some kind of valid document of gift, which can be a donor card, an advanced directive, a will, all of which, if that is something you are interested in doing, is not my favorite way of you making that gift. For the simple reason that we don't have our donor cards, our advanced directives, or our wills easily accessible to an organ procurement organization when we die. You are lucky if you die with your pants on, not to mention with your wallet on. So unless you're going to get a tattoo saying I'm a donor and what your a donor of, we would prefer, from the system perspective, that you be in the donor registry, like what you sign up for with at the DMV. But, if worse comes to worst, you can put it on a cocktail napkin, as long as your relatively sober when you put it there, and clear about what you want, and make sure that you have that with you at all times.

Something newish in our law, and I state newish because it's been in the law forever, but only enforced in recent years, is that once you make that testamentary wish, just like any other wish that you make in a will, the wishes of the donor are irrevocable by your family. So if there is one myth that I want to shoot out of the water, particularly for hospital lawyers, is the myth that — I'm signing up to be a donor, but if my mom doesn't like it she can overturn that. Because it is no longer true. The statute could not be more clear that no one else may revoke the wish of a donor. And organ procurement organizations and hospitals are now joining to enforce that wish because otherwise it's meaningless that you sign up.

If you don't make your wishes known before you die, any of the following persons in the order of priority stated can make the wish for you. And may make the gift. And this list, if you look at it and I will show it to you in a second, is going to look a lot like the people who would inherit your property if you failed to make a will, with some exceptions based on current day society and family relationships in a recently revised Uniform Anatomical Gift Act. So the way the list works if one dies without having registered, is that we look to the top person in the list, and if they don't exist, or we can't find them or call them, or commission a donkey to go to the village where they live and get them to a telephone within a timeframe that is compatible with donation, we move to the next person on the list.

So we work really hard to start at the top before we get to the bottom, and the people at the top are legally closest to you. They are either the person that you either appointed yourself or your agent; they are your spouse or domestic partner — your child. You work down the list until you get to some people who are absolutely strangers and those are the people who have the authority to dispose of your body, including hospital administrators.

In New Jersey, we have something really unique and actually utterly unique, which is that, in every state, we'll ask hospital administrators without any family friends, people who cared, identity. We would always ask the hospital administrator will you make a gift of this? And very often hospital administrators will say yes because if I fail to do that people would lose their lives, and my job is public health. So I'm going to say yes.

And besides when we poll society at large most people say that they would give, so most hospital administrators would say yes, but they're scared. And if you can think of yourself in that position you might be uncomfortable making that wish for a patient in the facility who you've never met. So in New Jersey the law states that if we've done our due diligence and we couldn't find anyone above a hospital administrator, that the hospital administrator shall say yes, so there is a state mandate for them to say yes unless they have reason to believe that the answer would have been no for that patient

So kinds of issues to keep in the back of our minds today, other than the issue of: "Have I made my wishes clear? Have I signed up? Have I filled out a donor card saying, 'No matter what, don't you dare take my organs'?" whatever you want to do that should be your primary question for yourselves.

So you go forth in your advising of clients on what to do, you need to know how to tell them where to go to sign up. And we make it very very easy, they don't really need a lawyer for that, but in terms of thinking of how do we save more lives there are a lot of concepts out there, a lot of things to be thought about in ways including, as we will talk about later, the ides of presumed consent. The idea of should we choose who[m] organs get allocated to based on their worth, as humans, their productivity, their ability to live long lives with that organ?

What factors should go in to deciding who gets those organs? Because there is a shortage, they are rationed, they are rationed to the organization created by Nova called UNOS. UNOS does it based on policy. Policies are created by amazing experts, we will hear more about that, as to who gets the organs, and why and when and under what circumstances.

Because every time someone gets someone else does not get. And that is a fact, and we hate to use the word rationed, but with a shortage, when some people are getting, that is, in fact, one of the things that happens. So how do we determine how to make the list run? Would it run better if we paid people for their loved one's organs, or if we paid states for their organs, or if we paid living donors for their organs so that they can give a kidney while they're still alive?

Or does altruism work the best? There is a system that is based on in the United States that is what the Anatomical Gift Act is about, it has been as effective as some of the presumed consent systems in other countries, but will it always be, or is it even fair that we are making tremendous and economically viable use of this donation that the donor is actually the only one that doesn't seem happy with it? And is there some kind of need for reciprocity, in other words, does the Golden Rule apply when it comes to organ donors? Should I be able to get on the waiting list when I was not actually willing to give my organs?

Should that be a rule? Should society pay for my transplant when I am not willing to give my organ or my family's organs. So all of these are the kind of questions that we need good lawyers to help us figure out, and you are about to hear from good lawyers and good doctors of how we've have done so far. Thank you very much.

Jennifer Walter: So I am, as Britney [Verga] mentioned before, Doctor Walter. I am a practicing physician and palliative care doctor as well as an ethics consultant at the Children's Hospital of Philadelphia, and in a room of lawyers you would not be surprised to hear that I am not able to talk about any of the patients that may or may have not been hospitalized at my institution.

But I do have much experience working with families and patients who have received organ transplantation. And I'm really grateful for the families that have come to speak to us today who were recipients themselves and who can give a lifeblood to the stories that these families have experienced. I want to echo the incredible need and amazing gift that comes from transplantation.

So what I hope to cover today, to build off of what Christine set us up with, is some information about the statistics of pediatric transplants in particular to think about one of the organs that has had a lot of controversy, at least in the recent past, which is the allocation of lungs in pediatric patients. So I want to look first at the policy around that and its justification and then move on to the legal challenge that was brought to that allocation policy particularly for children under 12 years of age, and then hopefully we can get back to it during our discussion section some of the ethical concerns raised by that legal challenge.

So just starting off with what it's like for a patient that may need to go and receive an organ donation, so patients that are in some organ failure need to make their way to a large medical center that has an organ transplant team. These are not uniformly distributed throughout the country and so for many people this requires that they move.

As you can see that for pediatric patients there are almost 1,900 patients across the country that are waiting for an organ. Some of the most commonly needed organs at this time are kidneys, livers, and hearts. And basically when they are evaluated by a transplantation team, the team determines whether or not they are sick enough or too sick to be actually put on the waiting list for an organ. This starts a long process of waiting and can be incredibly challenging. Families will often undergo, and the patients themselves, significant not only blood and other kinds of organ scan testing but even psychological testing because this is a long road ahead of them and the kinds of medicines and regiments that are necessary are particularly difficult for families to adhere to and so transplants, particularly in children, are really wanting to make sure that the child has a whole support system to not only make it through the transplant but the care afterwards.

And you may have noticed that I said that I am a palliative care doctor. And my experience with a lot of organ transplantation and waiting list patients is that we have automatic consultation for patients on many transplantation waiting lists because unfortunately we don't have enough organs to make sure that they are all transplanted and so here we have just the patients that did not make it to receive a organ donation in the year 2013. So a total of eighty pediatric patients across the country died on the waiting list.

Part of my role as a doctor is to prepare families for the possibility that they may not receive a transplant and to also to help ensure that their child has a best quality of life while they are on the waiting list.

There is a lot of discussion about who receives pediatric organs if a child were to die and what kind of organs children receive when they are recipients. And it's from an article in *Pediatrics* in 2013 that we see that basically a vast majority of organs received by children are coming from other children, which is the solid black line at the top. While adult donors do often gift organs that can be transplanted into children, the vast majority of organs that are donated to children come from other children.

When we move to specifics about lung transplantation, I just wanted to show you some data, the most recent data, from the organ procurement and transplantation network in 2012 when they were looking at donors that had started on the list in 2009 and what happened to them over the following three years. The top dark green, about 10% of those three years were removed from the list, most likely because they were too sick, although some of them maybe because they improved and did not require transplantation. Another approximately 50% who actually died while on the waiting list in that three-year period. And then you can see the bottom in the lightest blue, that up to 10% of those that started on the list in 2009 were actually still on the waiting list three years out. I know this data is consistent with the data at Children's Hospital of Philadelphia, checking in with our lung transplant team they said that we have a 52% mortality risk for patients waiting on a lung transplant list there.

So, lung transplantation is a lifesaver, and organ transplantation in general is. Unfortunately it's not going to extend the child's life as long as their life span would have been if they hadn't required it. And, for lungs in particular, which have one of the shortest, I guess you would say half-lives of any organs transplanted, by about 5 years, a little over 40% of patients will no longer be living. And so it's important to realize that we're still collecting data for many of the recipients who received transplants ten years ago, but only about 20 to 30% of those that we have data have survived ten years with one lung transplantation. Many will need to go on to receive a second transplant to stay alive at that juncture.

So now we want to move a little more into your realm, which is talking about some of the regulations around transplantation and how they affected children. A more general federal law, the Children's Health Act, was passed in October 2000, and that really called on the Organ Procurement and Transplantation Network ("OPTN") to develop specific criteria, policies, and procedures to address the unique needs of children. Prior to that there hadn't been as much focus on how children's needs and transplantation may be different. This resulted in several different changes in organ allocation, some which I'll talk about in more detail regarding lung allocation, but specifically also for liver, kidney, and heart transplantation.

So now I'm going to move into the regulations around lung allocation. And this is part of, again the OPTN policy 3.7. OPTN, as Christina [Strong] mentioned, is basically the regulatory body that is responsible for creating the lung and other organ donation allocation policies.

So, for lungs, over the years they moved first in 1995,from an allocation based merely on time on the waiting list and blood type to after the NOTA that you mentioned, the National Organ Transplantation Amendment, that basically organs needed to be allocated by best use, and so best use wasn't merely time on the waiting list, but other kinds of factors that included likelihood of survival and risk of mortality without the transplantation. And so the allocation policy was revised and led to two different classifications and ways in which the lungs would be allocated. So for people that were twelve years or older, they developed something called a lung allocation score, which can be a number from 0 to 100, with 100 being the sickest or most severe need for a organ, the blood type, and then geographic distance. The development of the lung allocation score I'll talk about in a minute and its justification.

Because of several different reasons, children under twelve they decided should not receive a lung allocation score. And, so they basically developed a two-tiered system within that group where children who are the most sick would be given priority one, and children who were sick enough for transplant but not the most sick would be given priority two, and then also they would be stratified by blood type and geographic distance.

For patients in priority one, time on the list does matter. If you're on the list longer that's how it breaks the tie, if you're in the same geographic region and have the same blood type, you're basically designated as the first on the list if you've been on the list longer. In an attempt to try and ensure that pediatric patients would have access to the organs, when they created this "under twelve designation," they said that those in that category got first priority to receive any offers from any donors under twelve within a 1,000 mile radius. They then got second priority for any adolescent donors, which is a teen from twelve to seventeen within that radius. And they would be last to receive any organs from adults that had, basically would have to have all the adults on the list would have to decline before a patient under twelve would be eligible for an adult lung.

Now there was a system put into place for an appeal. The transplant center — individual hospital — can basically appeal to the lung review board, but that was intended for instances where a lung allocation score didn't seem to accurately reflect the kind of severity of illness that the team perceived to be the case. It didn't offer, in any way, an opportunity for patients that were under twelve to appeal that they should be treated like an adult. And that basically is an important part of the legal challenge that we'll discuss.

So, how did they come up with this lung allocation system, what was its justification and the policy in general? Well, as I mentioned, they were tasked with trying to create a system that was really intended to get the net benefit for the potential recipients on the waiting list. And, the goal was to really have those who had the most urgent need to have the greatest chance of success. And so, in the development, they had quite a bit of process to try and determine whether or not there was agreement that the lung allocation score was a fair way to do this. They had a sponsoring committee who developed this complicated algorithm of scientific components of lung function and other infections, et cetera. It was done with a big consensus conference that they discussed the lung allocation score. They had to present it to the board of OPTN. And then eventually, any policy they make also has to go to the Department of Health and Human Services Secretary, who can decide to enforce or reconsider any policy. So the lung allocation score and the division between the over twelve and under twelve policy was reviewed through all these mechanisms before it was put into place.

The reason they had decided not to use the lung allocation score for children under twelve was that there was, in general, believed to be a different set of diseases that particularly young infants have that are never seen in adulthood. And there was a concern that the kinds of criteria they were using in adults, to determine this area of illness, weren't applicable to small children with these less common kinds of diseases. In addition, the number of children requiring lung transplant is very small, and so the amount of data we had about what their severity of illness was, or what their prognosis was, was also much harder to extrapolate. And so the concern was that the lung allocation score, which they had adequate information to validate in the adult population wouldn't necessarily apply in the other children who had different kinds of disease for some parts, and also just smaller group overall to see whether the score would be validly apply. And so the intention had been that when they reviewed this new lung allocation score, and in 2008 they decided that they wanted to offer further protection to pediatric patients, and that's when they instituted both, the priority one and priority two system, and then they also decided that adolescents from twelve to seventeen years would preferentially go to pediatric patients before adults.

So both of those things were put into place again in an attempt to ensure the safe and fair distribution of lungs to children. However, there are still, unfortunately, many young children and children at that cutoff age at perhaps nine to eleven that needed lungs, and sometimes these situations become incredibly dire. And I know that there have been attempts made by different transplant centers, the pediatric transplant centers, to address the question of whether this was the most appropriate system to thoroughly distribute organs to pediatric patients, but at that time, UNOS had delayed further evaluation and said that they would do, in their annual review, an assessment of whether or not it was really an appropriate, based on the best evidence available, system.

However, there was a large amount of media coverage that came around one particular patient. The family, Sarah Murnaghan's family, were able to appeal to the social media to ask for support and to really draw attention to the concern that patients in this near-twelve age range were not eligible to receive adult lungs unless all other adults had refused them, and they felt that this was highly problematic and would lead to their child's death. So, the Murnaghans basically took their case to federal court in the U.S. District Court for the Eastern District of Pennsylvania. They had a suit against the U.S. Department of Health and Human Services and Kathleen Sebelius, in her capacity as Secretary, and the Murnaghans raised two particular concerns at that time.

The first was that UNOS rules, that OPTN policy that I had mentioned, reflected what they called an "age-based" discrimination. Second, they argued that the transplant selection committee that happens at individual hospitals lacked transparency and fair decision-making processes. And that, because of these two things, that there should be a restraining order placed against those who are trying to prevent allocation of adult lungs to their child. And so, basically, this civil action resulted in a federal judge, Michael Baylson, issuing a temporary restraining order during the hearing on June 5th, 2013. His commentary on this was based on two different things. One is he attributed the expert testimony by the head of lung transport group at Children's Hospital of Philadelphia as arguing that the twelve-year cutoff was really arbitrary, especially as it applied to children from five to eleven years old who had a disease found in adults, and that these children could receive lung transplants with donor lung reductions, and that basically this is where an adult lung is reduced in size to fit in the chest cavity of a child, and that their survival rates and long-term outcomes essentially would be the same as adults.

The second thing that Judge Baylson referred to was that OPTN, as a result of the petitioning by the family, had basically scheduled an emergency meeting for June 10th, five days later, which he believed suggested that there were some legitimate questions about the fairness of the policy, and the data that they had. And so, he stated that the temporary restraining order was in the interest of the public more generally, as well as the plaintiffs in particular, and was not in any way intended to dictate when and whether Murnaghan would receive a lung transplant.

So some of the data presented by OPTN at the meeting on June 10th seemed at least concerning to the possibility that there was differential results or outcomes for children in the six to eleven age range compared to the adults over eighteen. So on the left-hand side on the y-axis, we see a relative risk of death because of patients too sick, or they're too sick, against their age on the x-axis. So the middle one is age six to eleven, and while it is a slightly higher risk than the black line, which is the risk of being an adult and dying on the way to transplant, it really isn't statistically significant, which isn't surprising given the small number of patients. So, we don't have good evidence to say that they're dying more than adults are on the waiting list, but on the right-hand side in this scale when you look at the y-axis, which is the relative likelihood of receiving a transplant, the six to eleven age group is below the dark black line, which is the risk if you are an adult. And so the concern was that children six to eleven were less likely to get a lung transplant than adults were or even children in the twelve to seventeen age range.

So Steve Harvey, who was the lawyer for the Murnaghans, and there was another patient that he had also started to represent, Acosta, spoke to the executive committee of OPTN in this emergency June 10th meeting. In that meeting, he argued for an interim policy change that would basically allow for children like Murnaghan and Acosta to receive an organ transplant from an adult without having to wait for every other adult to deny it. He argued that this would be a life-saving change that could save some, well recognizably a small number of children, but still save some children's lives, and that he argued the potential good would outweigh any effects that it would have on the system. He argued that reviewing this policy would demonstrate more fairness and that would therefore have an increased confidence by the public in the system. His argument, in general, was that basically there should be some mechanisms for patients, acting through their transplant teams in the hospital, that would basically allow them to get a lung allocation score and be listed as an adult with that score, but not at the same time lose their opportunity for a lung from a pediatric donor, as well.

So there are several legal claims that they made in an attempt to argue for this. Basically, they were trying to determine whether medical evidence actually justifies the hard cutoff and exclusion from the medical severity principle, or, like the data that the OPTN demonstrated, there might be some question that the medical data now is indicating that there might be some differential preference. And they were referring to the 42 C.F.R. part 121, where basically it was OPTN's responsibility to make available. whenever feasible to promote organs, make organs available whenever feasible to the most medically urgent patients who are appropriate candidates for transplant, and that it was appropriate for them to suspend their current policy based on a risk to the health of patients or public safety. The Acostas's lawyer and Murnaghan's lawyer was not, however, arguing that they should receive any kind of special preference, but that they would have the same chance to receive a donated lung under the same principles that apply to children twelve years or older.

At the time of the request, there were sixteen children age six to ten that were seeking lung transplants that might have qualified for this. At the same time, there were 1,600 adults seeking a lung transport, thirty-nine of whom were between the ages of eleven and seventeen, so I think the families were looking at these numbers and thinking that unless their children were really considered in the same pool as adults, they wouldn't really have access to adult lungs.

So in this June 10th meeting, the ethics committee of UNOS also issued a statement that highly criticized the legal action that was being taken by the Murnaghan and Acostas families. They describe in detail the two primary ethical principles of allocation and try to justify why the system shouldn't undergo legal challenges. The two main ethical principles that they often talk about are utility, which is a maximization of benefit, and I don't know if any of you have studied utilitarianism, but this is the concept here. And utility could be actually defined in a series of different ways, so it could be minimizing the deaths on the waiting list. Utility could be maximizing the expected users of survival post-transplant. It could be maximizing the number of organ recipients, or maximizing the additional years post-transplant versus not being transplanted. But they perceived that the legal dictate was that they were to maximize the best use of an organ by NOTA in the final rule. And so they interpreted it to mean that, really, if children were to have the best chance of survival by having smaller lungs because of the kind of risks of reducing the size of the lungs and the kinds of outcomes that they would have, meaning they would have a greater chance of long-term survival with a smaller lung, that that should be the criteria that is used, and therefore, maintaining their first preference for pediatric lungs and having adult lungs be primarily going to adults was the appropriate standard. I think that, using their own logic, this would require good evidence, which at the time, I think, and even today, there is still a question as to what the best evidence demonstrates, and so, we could use a similar ethical principle, but have a different answer, depending on what the data, or what we discover the data, to be.

They also appeal to the idea of justice, and how we distribute very valuable resources, like organs. And they describe a principle of justice to be treating like people alike, and they acknowledge that there could be morally relevant differences between people on the waiting list, and that, as a result, if there are morally relevant differences, that there could be an unequal distribution of resources. This doesn't require that everyone receives the same thing. And so, they appeal to a concept of equality of opportunity, that really anyone that's in need of an organ should be evaluated, and then determined about whether or not how they match up to the standards of best chance of survival and most sick, and that it's that opportunity that is essential, not the outcome.

However, there are others that argue, particularly with children, that you focus on something like a "fair innings" standard, meaning that we'd all want someone to have a certain amount of time, or at least more time, a fair number of innings that they experienced. And so, a potential recipient, who is in their thirties or forties, has already lived a longer life then a child that is five or ten, and that we should give as many young children more opportunity because they have yet to have their fair innings in life. And so, this is one of the arguments for giving special consideration to children when doing organ transplantation. Other kinds of things include, particularly with organs that have a long life with the recipient, they may get additional years of life as a result of being transplanted younger versus someone who is already near the end of their life and would potentially die from other causes, as well as the fact that we have good data to show that children who are transplanted earlier have better growth and social development outcomes then children who are sicker in the hospital for longer periods of time.

UNOS's ethics can be acknowledged that sometimes these principles actually come into conflict, and while they offer a couple of organized principles for how to deal with those conflicts, in the end, they think that this kind of special review or appeal that went through this legal challenge is actually very detrimental to the whole allocation process by undermining the thoughtfulness and transparency that went into the development of the policy. And they thought that it was very problematic, as well as others who have raised concerns about which kinds of families would be able to lobby such a large legal challenge and have the sophistication to be able to do that, so there may be a preferential ability for wealthier and more educated families to be able to lobby on behalf of their children or themselves.

So despite UNOS's ethical, sort of, clear statement that they didn't support the legal challenge, the debate that's occurred continuing from there has not been entirely clear. So there continues to be ongoing discussion about the best way to analyze the very scarce data we have about outcomes for children on the lung transplant list. And, while many, actually, dispute the fact that the data that was even presented at the UNOS meeting of children being less likely to receive the transplant as inaccurately calculated. By that, I mean they did not believe there is a difference for children six to eleven either in dying on the transplant list versus an adult or that they are less likely to receive a transplant than someone older, and so that in many ways may undermine the initial challenge that the case brought.

However, there were other questions that were raised about the system as a result of this incredibly close evaluation that came about, and one of them was the question of whether many of the pediatric lungs — there are enough pediatric donors to meet the pediatric recipient need. However, they're not well enough spread out across the country, so in certain areas, patients are waiting on a list, and they're not able to be eligible to receive the organs that maybe are a couple of states away because of the 1,000-mile radius limitation, so maybe Jan can speak more to this about the complications of having organs travel long distances, but some people have criticized or been concerned about the possibility that maybe we don't have a wide enough radius that organs can travel, and that perhaps it would be safe for pediatric organs to travel further to make it into other children's lives. And then, there's also concerns that were raised by the Murnaghans about the level of transparency in transplant committees, and whether or not there should be more of an open communication between the family and the transplant team about what actually the patient may or may not need for her development of the criteria. And I think that while there's been a large amount of concern for how the legal challenge could affect the trust in the system, many people acknowledge that it is understandable that an individual family or set of families would do their utmost to advocate for their child, and that, as a result, it's incumbent upon the legal system to determine whether or not they are going to allow these kinds of appeals, rather than expecting families not to appeal.

So, the result of this June 10th meeting was actually a policy change, and a policy change has been in effect since then. It is that the lung transplant programs can now submit a request to the lung review board for a lung allocation score for children less than twelve that they believe would be a reasonable candidate for an adult-sized lung, and if they had a disease that inconsistent with the kinds of criteria that the lung allocation score uses, so things like cystic fibrosis, which occur in adults as well as children, there is a reasonable expectation that the lung allocation score would work appropriately in those patients.

So that is my portion of the time. Thank you. [Applause]

Jan Weinstock: Hey everybody. So, I am going to take a little bit of a different perspective on this. Number one, on the Sarah Murnaghan case, how many of you actually followed it while it was going on? You were exposed to it in some regard? Yeah? Okay. Okay, so here's a couple of comments about it. The Gift of Life donor program, we coordinate organ tissue primarily from the eastern half of Pennsylvania, the southern counties, as Christina mentioned, and also the state of Delaware. So the Children's Hospital of Philadelphia falls within our donation service area, and we are primarily responsible for coordinating organs that would be made available to patients at the Children's Hospital. So, like Jan, I wouldn't comment on any specific case. I will say this, that I think the Sarah Murnaghan case has changed the face of transplant and in non-legal ways. So certainly, there was a legal challenge, and I would encourage you to actually go online to the district court, there is a transcription and an audio of the hearing itself, and it is very interesting.

It is interesting in terms of what evidence the judge actually heard and how quickly it was decided. It is significant from a non-legal perspective in terms of the use of social media, and Christina and I were just talking, as a parent, I would applaud the Murnaghans because I believe I would want to do everything out there to advance the interest of my child if he were chronically ill. As someone who sits on the other side and has probably a responsibility towards everyone on the list, there may be certain aspects of the social media that are troubling and some of the aspects that are relevant are this family, and again, as a parent I would probably do or want to do everything for my child — this family was able to harness the power social media. And that is very, very powerful — in order to draw resources in terms of how to ensure that their child got the best possible chances for life and I think we all want that for our family members. Not every family has those resources available.

Secondarily, as part of this social media campaign, there was certainly a request that individuals engage in what is called directed donation. So, Christina spoke about donation and about a gift and that gift. Typically people say that gift is available and don't identify a specific individual to be a recipient as it relates to a deceased organ donation and let it be available to the person who is most in need. As part of some of the social media campaigns that have been initiated, there have been requests by individuals that some other family, at the time of their loved one's death, earmark an organ for them. And that's troubling to me because we have a very finite resource here as we've spoken about. From an ethical perspective, I find it very troubling. So now the person — are we going to engage or permit behavior where essentially the person who shouts the loudest who has able to send the broadest vast of messaging that they may be able to jump the line because directed donation is absolutely something that is permissible under our system now?

So, there are many legal issues and ethical issues where there is overlap in our area and it brings it to my presentation that I want to highlight for you. The reason we are focused on these issues are because we are talking about a scarce resource. If we had an unlimited supply of organs, we would not be having these discussions. So, I want to talk about what lessons there are from around the world and what you would do if you were sitting in our shoes in terms of having input in how the system might work. So, first about Gift of Life Donor Program. I identify our donation service area; in the red here actually speaks to the numbers. So in calendar year 2013, in our donation service area, 447 persons went on to become organ donors after their death. How many people are in your law school class? In your law school — how many students?

Audience Member 2: 750.

Jan Weinstock: 715 or 50?

Audience Member 2: 50.

Jan Weinstock: [7]50. Okay, so we're talking about an amount that's sort of slightly more than half of your class, right? And, you may not think that's a big number. There's many, many law schools out there. None I'm sure as fine as the class that you have here. I'm sure the graduating class is probably the finest class ever, possibly. You look like you're laughing. Are you a professor?

Audience Member 3: Yes.

Jan Weinstock: Do we have any 3Ls here? You need to get on him, unless he's a faculty advisor! In any event, my point is this: you may not think 447 donors. You may not think that's a big number. I am telling you that is the largest number of organ donors in any donation service area in the United States in 2013. This community, in which you are living. is the most giving community in the country. So that 447 yields 1,228 transplants. So, you heard Tom [Gano] and Russ [Jackson] talking about an individual donor can give eight organs for transplant. Not every donor is what we refer to as the "perfect donor." So not every donor goes on to provide for eight transplants in addition to the tissue transplants that Russ [Jackson] was referring to. So, we are talking about numbers where every single one matters. Christina [Strong] focused you on the fact that every single hospital death is called into our organization. Did you know that? Did you know that every single hospital death is called in? So we get, on a yearly basis, we get around I'm going to say 40,000 phone calls. You know I don't know what number — 40,000 we get.

Audience Member 3: I thought it was over 50?

Jan Weinstock: It used to be. 40,000. 40,000. So, we'll go low. 40,000 yields 447 organ donors. We are looking at a needle in a haystack. We are also looking at the fact, as Christina said, we have eighteen people dying each day, and if you view it through the lens of those individuals who got too sick while they were waiting and they can't be transplanted — thirty-six people a day. We in this room are all collectively responsible for those people because we have the ability to put that donor designation off. So, I want to take a global view for a second or for a couple of minutes actually. So internationally it's estimated that between 12,000 and 15,000 people die each year waiting for an organ. This is hugely understated. Why? Because in the United States we keep these statistics. If you go onto the website unos.org you will find more information about donation and transplantation that any other country has or provides.

You know Jen [Walter] had mentioned concerns raised by the Murnaghan family about transparency within hospital processes. I will say to you, in my opinion, I think donation and transplantation is the most transparent specialty in medicine — in terms of the information available as it relates different centers, the number of patients who are waiting, the number of patients who have been transplanted. So, it's estimated there are about a quarter of a million patients worldwide, and this is in those countries that maintain a list. Because if you believe that many countries have the same system — the list, the infrastructure —that we have in the United States, you would be incorrect.

So, where are we in this? We have this worldwide shortage, and the United Nations has recognized that there is a public health crisis, that there is a worldwide shortage, and that as a result of that, there are consequences that are considered to be morally, ethically unacceptable in terms of behaviors that follow that shortage. And in 2009, the World Health Organization had started putting together or continued reports, or continued reports, on the fact that there must be an elimination of what is referred to as transplant tourism, theft of organs for transplant, the commercialization of transplantation.

So, let's first stop at India. This individual is showing a picture. This is an individual who went on to become, who had become a living kidney donor. I don't know if you can read this far. He was paid $2,500 for a kidney, right? Because he was told "you have two kidneys, you only need one, have money so that your family can be fed." There was an absolute absence of information provided as it relates to any aftercare that might be needed or what it would mean for his own health. So, we have individuals who become donors because there is a demand, right? There is a demand here.

How are we going to meet this? How will we satisfy the demand that's out there? The individual who was the mastermind of this operation of coercing, encouraging, threatening individuals to become living donors actually was picked up. But this is not an isolated case in the international scene, alright? It is a problem. It is a problem in certain countries the issue of coercing and the buying and selling of organs. Kosovo, there has been broad allegations and some in fact convictions that individuals as part of, you know some of the ethnic cleansing that took place, individuals actually went missing and organs were recovered from them and sold in order to assist in funding the war itself. Okay? So we're talking about crimes against individuals layered on top of genocide as well.

In the United States, so for Christina [Strong] and myself and Jen [Walter], we have been involved in this field for many years, and it is an anathema to us if we believe that the buying and selling of organs were taking place in the United States, because we will not succeed in transplanting those folks that are waiting on the list if there is a lack of trust in the system or if people believe that there is a way around the system. And, in fact, the first reported case in the United States of buying, of human trafficking of kidneys, occurred in 2009, and subsequently this individual plead guilty. And I think really he was only incarcerated for two and a half years. So he had, the individual who was the trafficker, had collected over $400,000 in terms of trafficking of kidneys. And what his scheme was: he would identify individuals from other countries, so in the cases that were documented an Israeli young man came to the United States, and again it is illegal in the U.S. to buy and sell organs, so there was a story that was fabricated that this young man had a relationship with the candidate who was the recipient, and that they were friends or that they had an extended familial relationship. So part of what takes place at the transplant center is very extensive psycho-social evaluations in determining whether individuals who are going to be living kidney donors — what's the motivation and what's the purpose. So there are many centers in our area who do living donation, and there are many instances where they will reject someone who comes in and says "I want to be a living kidney donor for my friend here," or " I just want to be a good Samaritan living kidney donor," if the transplant team and the social work team does not believe that the motivations are clear and consistent with the law, or they believe there has been some type of undue pressure, or they believe that it just may not be safe. But this is a problem, so there is intense scrutiny to ensure that there is no buying and selling.

We know we need to increase the organ donor pool. Unless you have some additional suggestions, these are the only solutions that we've been able to identify, and let's deal with the bottom one first. There are efforts being made to produce artificial organs, and particularly using tissue, there have been advancements. I think it is going to be some time before we see artificial organs. So, in terms of the next ten or twenty years, I don't believe this is going to be the answer. So, we could increase the number of deceased organ donors and the number of living donors. If you're a living donor, how many organs are you making available for transplant? If you are a living donor?

Audience Member 4: Kidney and liver.

Jan Weinstock: Pardon?

Audience Member 4: Kidney and liver.

Jan Weinstock: So kidney, so if you're a living donor, you can be a kidney donor or you could be a living liver donor, but the number of living liver donors or donations is pretty modest because the risks associated with living liver donation are significantly higher than living kidney donation. Alright?

If you were a deceased donor, we've already heard how many organs can be transferred from an optimal living, excuse me, deceased organ donor? Right? Eight. So, there's more yield, okay? I mean you must have an economy class that you take too. So the focus on where are we going to really provide for the maximum number of transplants, we have to increase the number of deceased organ donors, but you've already heard from the other two panelists that it has to be a certain type of death that allows for deceased donation, so we might as well also look at the living donors as well, living kidney donors, to maximize those numbers.

Okay. So, imagine this is your chart, you're going to have to figure it out. So the first thing you would do is you would look to see what else is out there, right? And you would look at the donation and transplantation rates. So what do I need? How are you going to be able to measure whether a system is available? We could talk in gross numbers about how many people are on a waiting list or how many people went on to become donors, but there has to be an objective standard that you can look at universally to see how are we doing comparatively. So the current standard, and I don't know that it's the perfect standard, the current standard is people look at how many donors per million. It's a population based numerator-denominator, with the numerator being the number of donors. So, first thing, opt-in or opt-out. What kind of system do we have here?

Audience Member 5: Opt-in.

Jan Weinstock: Opt-in. Right? And you heard Christina [Strong] explain it. So, you know what the opt-in is, you know what the numbers are, Christina [Strong] gave you a visual on what it looks like for the number of people who died. This is the visual on what our current waiting list looks like: all these stadiums. I just wanted to point out for a minute how long people are actually waiting. Does anybody have, do they know anybody who's waiting for a transplant here? Okay. So, possibly.

Most people who are on the waiting list are waiting for kidneys. The average wait for a kidney is 5 years. That is a long time. And while that five years is taking place, people are on, typically on dialysis, and their health suffers. So we've already heard again what happens as one's health condition worsens, with the likelihood of being actually eligible for the transplant. So these were deaths, let's keep going.

We know what our current system is; Christina [Strong] focused on the opt-in system. It's all about the authorization, whether the individual designated themselves, or whether their family does it in the absence of the decedent having made the decision, and she focused on what we call this autonomy: if I make the decision, no one else in my family can reverse that, and that is important. I would emphasize what she said as well, you must understand that, it counts with the decision that you make. So here's where we struggle a little bit in this opt-in system. This is a 2005 Gallup pole and there have been subsequent ones. Every single time there is a Gallup pole on: "Would you be likely to become an organ donor; do you think it's a good thing?" Overwhelmingly, people say "yes." And then, when it comes time for the Donor Designation on the driver's license, these percentages do not look like those percentages you just saw, do they? This percentage was up here. I don't see anything remotely looking like those rates.

So why is that? So we have those myths, which is why our volunteers are so extraordinary, because they're out there trying to dispel these myths. These are the myths that we believe are the barrier between individuals sort of saying "I think it's a good idea" and then what happens when they go to the driver's license center.

The number one — take a shot, what's the number one myth of these, these are all myths okay. Number one (pointing to audience member).

Audience Member 6: Two.

Jan Weinstock: What are you saying, number two? I can't tell.

The myth — if I have it on, they won't save me. Absolutely correct. Does. Is that true? No.

And by the way remember what Christina [Strong] said, which is a great line, you are lucky if you have your pants on when you are having, you know, some, some traumatic event. The hospital doesn't know whether you had the donor designation. They don't know that. Your wallet isn't anywhere near those treating physicians, and it's the organ procurement organizations are the only ones who actually have access to the driver's license registry data that's maintained by the state. Okay, but that one, this particular myth is a struggle. So I'm going to pass on this for a second. So if we go back here. The bottom line is this opt-in system, is it working? So I see, you know, maybe not so great. Okay, so the opt-out system, what does it mean? You're in unless you take yourself out, right?

So in many European countries it assumes donation, unless the deceased has opted-out and there is an affirmative opt-out that the individual, while they're alive, has to take. And, based on the survey that I have done, there are so many variations on it. So there's this pure one where really the person, if they haven't opted out, the physicians will move forward or there are soft, this soft version of it where it said, you know, this is what the law says, but this isn't exactly the way that we are going to address it.

Alright, Austria has a pure, so that means if you have not opted-out, the physician, and you are eligible to become an organ donor, the surgeons will proceed with that recovery. So if you look there's the fourth bullet point here: if there is doubt as to whether the decedent opted out, if there's any question, removal is permitted.

In the U.S., where we enjoy freedom of expression; where we are all about self-determination. If an individual hasn't made their wishes one-hundred percent clear, what do you think happens? Do you think everybody proceeds? No. It's just, it's not, truly, it is not our thinking here and we really have to focus on this issue of having people make the decision, make it clear, at least so it can be acted on.

So what this says down at the bottom, I don't know if the red, if you can you see the red, was before they moved to this system, they were at 4.6 deceased donors per million and they moved to 22.5 donors per million in 2012. Pretty significant spike.

Okay. France has this soft-pure, which is the reverse. Meaning that, well it's the reverse of what happens if there's any lack of clarity then typically the hospital will not move forward and the last bullet point it says in the absence of opting-out, the principle of presumed consent will hold. However, so you know what however does, it completely cancels out everything that came before, in practice, doctors still inform families of the option to refuse. So that's what makes it soft. France has a deceased donor rate of 24.9 donors per million. Which is, I'll show you a comparative chart, which is sort of middle of the road.

Belgium is soft. So again there's all these different variations on how you have, if you have an opt-out system. So they have the national information campaign, which is significant because you've got to marry what's going to happen and what people understand and think is going to happen. What's significant here is it says fewer than ten percent of the families actually refuse donation, and they have a deceased donor rate of thirty donors per million, which is certainly higher than the other countries.

Okay. Spain is typically touted as the most successful system in Europe. Alright. So, and Spain was one of the early adopters of this opt-out model. Now what's curious here is, this says it's a soft version. So here's where what the law says versus what the practice is. You know, you folks will run into this throughout your entire career, there is a gap at times and your job as an attorney is to figure out how to close that gap. The Spanish Model is that if you opt-out, okay that's fine, but you're in unless you opt-out. Donor's doctors approach the families, inform them of their option to refuse donation on behalf of a decedent who had not already opted-out. That's what makes it soft, but familial consent isn't required for donation.

So again it's a little wishy-washy if you look at it just on paper. If you ask folks who are part of the health care system in Spain, the single most significant factor that causes Spain to have such high donation rates is the medical infrastructure that is supporting this process. That they have physicians who have specialized knowledge and experience in the different hospitals who are acting on the donation opportunities immediately, in a sense of communicating and stabilizing the patient, and that it is not so much the fact of whether they have the opt-out system. It is the fact that they have this network of transplant coordinators and medical experts that are supporting the process, and Spain has a deceased donor rate of over thirty-five donors per million. So as a country, Spain has consistently been a leader.

So there are a number of other countries that, just from the legal perspective, are fascinating because drafting this type of legislation has to be interesting. So Singapore has this hybrid approach where presumed consent only applies to kidneys of victims of fatal accidents. Okay. So most people awaiting transplant are awaiting kidneys, the presumed consent only applies to individuals who were victims of fatal accidents. and in all other cases they're looking then at family for authorization. So it also speaks to the fact as to who determines if a patient is brain dead et cetera. So a relatively small country in terms of the population issues, but an interesting approach that they have, and what's also interesting here is that the system provides for the opt-in donation of other organs, which we spoke about. Individuals who have not opted-out get priority on the waiting list.

So Christina [Strong] and Jen [Walter] raised the issue of what other kinds of incentives are meaningful. We know that there are financial incentives in other countries. Are financial incentives the way to go? This is a non-financial incentive. Right? If I, if I believe that in some point in the future I may need something, I sure want to put myself in the best position for that.

Immediate family members of donors receive a fifty percent subsidy for medical expenses for five years following donation. So certainly a financial incentive there. Singapore has a deceased donor rate of five donors per million. So it seems kind of tiny. Pretty sophisticated or complex approach.

So I point out these different countries because there is significant variation in this concept of opt-out and time and time again, for those of us who are involved in donation, we hear people propose the answer is presumed consent. And based on the data, I'm not sure that I personally think that's true. Okay, so this particular slide is showing Spain on, here's Spain right here.

Okay, so this particular slide is showing Spain on, here's something right here. Okay? That purple is Spain, and in 2012, Spain had, this is for 2008, so I'm going to give you updated for 2012, Spain had thirty-five donors per million population, alright? And as you can see it's pretty significantly high above everybody else. United States, as a country, right there, twenty-five donors per million. The far right, that white bar on the far right, represents this donation service area that you are in, that has in excess of forty-four donors per million, okay?

We do not have an opt-out system in this donation service area. So, what does that mean? It means that you need to marry incredible medical expertise. You need to marry community commitment. You have to have transplant centers that can support. And it means we still aren't doing enough because we still have people dying every day.

So, what else should we be doing? How can we tweak the system? And I highlight this again because I don't think the answer is just opt-in or opt-out. I think we have to look at what other factors and variables do we layer on this to make sure that we put these people on the waiting list in the best possible situation.

I'm going to flip to a slide here that talks about some of the different types of incentives that have been utilized, and then we'll just take a look. And then you guys will rewrite the law. Sounds fair, right?

Okay. Direct payment. So we know there are some countries that allow direct payment for organs. Although certainly, the World Health Organization is moving to discourage that. We have reimbursement or payment for medical and related expenses for living donors. So, if you become a living donor, we will reimburse you for your expenses and then the question becomes: well how long would you do that for? Would you do it for a year? Would you do it for two years afterwards? What happens five years? Do you do it for all complications, and then you can imagine trying to tie some condition you have to the cause, that is, was the actual being the living kidney donor the cause of whatever symptoms you were experiencing. Provide living donors with the deduction of up to $10,000 for expenses relating to it. So, is there a way to work within the existing tax construct to encourage people to become living donors? And some of these we actually have in our region, including providing employers with tax credits if they allow people paid time off to go ahead and become a living donor. Have an individual who had been a living donor have a priority on the waiting list if they, themselves require an organ, which is also currently embedded in our system here in the U.S.

Israel does things, besides which was, I think, noted earlier, the concept of the Golden Rule. So, in Israel, if you are waiting for a transplant, you have certain priority if you had already designated yourself a donor, or if someone in your family was a donor. Again, is it okay for you to receive if you are not willing to give? And I know this is something that folks within our perspective clients have given a lot of thought to.

Again, right now the struggle in the U.S. is, the system says that allocation can only be based on what? Medical criteria. So this issue of, would you — the Golden Rule issue — flies in the face of, it's not really medical criteria.

So here are some other additional incentives that have been explored or are currently in place. We talked about what happens in Singapore, reducing health insurance premiums if someone is an actual donor. Discounted driver's license fees, there was, who was that, in Georgia? A while ago, they were doing discounted driver's licenses if you put the organ donor designation, and it was overturned, not because it was perceived as buying or selling or somehow coercing people to give organs, but it was considered unconstitutional in terms of how it was allocating the burden among taxpayers. So, it was a constitutional challenge to it.

Life insurance policies. So we've had a couple of folks in Congress who have said, hey, how about we consider that for every person who becomes a donor, who actually becomes one after their death, not just put it on their driver's license, we will have a life insurance policy, the proceeds of which they can use to designate to their favorite charity. It might encourage people to move ahead. Access to parks, and access to memorials, or sort of advanced time on the waiting list, we talked about these. Any other incentives that you can think of? I'm serious, because we're willing to consider just about anything. Doesn't mean that we'll take it into a law, but what else? There's money. What motivates people? Money. Love for their families, so maybe if I thought that my family would get a leg up on something. What else?

Audience Member 7: Student loan forgiveness.

Jan Weinstock: Student loan forgiveness, that's phenomenal. Seriously, that's brilliant. Maybe some sort of reduced interest on something. Okay, so, let's just for the heck of it, okay. This is the U.S., we're here now. Let's just take a vote, alright? So you're gonna ask, we're gonna do a show of hands if you want to opt-in, which we currently have, or opt-out, alright? And everybody has to vote, okay. And this is not recorded, this part alright. Okay? Who wants an opt-in system, the one we currently have? Who's voting for it? One, two, three, four. Oh come on, that's like half. I don't know what that is, you, back there. [Laughter]

Jan Weinstock: Go for it, go for it. Alright. So we have about six — five or six. Who would support an opt-out system? The overwhelming majority of you. Okay, you can put your hands down. If you are prepared to support an opt-out system, just curious, me, what would you do to support it, literally, what would you do? Shout, I can't hear. What would you do? What would you be willing to do? Would you be willing to tell people they should? Yes, yes.

Audience Member 8: I mean, I guess I would, you know, go and lobby for it, and have these sort of discussions, but more than that I would draw a comparison with the rest of our health care system. I mean from my perspective, and perhaps I'm wrong, for the majority of things, we have to opt-out of a lot of things. Like, if I want my mom to have access to my medical records, I have to put a letter saying she has access to my medical records, unless I'm in some type of dire situation, or if I have to say she's my next of kin, blah, blah, blah. But I feel like there's so many different aspects of our health care system that we actually have to go ahead and put in writing that we want that not to apply to us. I don't understand why this can't also, I mean, I do understand, but in a sense, I think that it's not that far of a reach to expand it.

Jan Weinstock: Anybody else? Okay, thank you for sharing that. So, yep.

Audience Member 9: I would raise a question. Can we opt-out from autopsies?

Christina Strong: From autopsies? On religious objections, yes.

Audience Member 9: You can?

Christina Strong: Yes, you can.

Jan Weinstock: Yes

Christina Strong: For autopsies.

Audience Member 9: In the United States?

Christina Strong: Yes.

Jan Weinstock: In certain circumstances.

Christina Strong: In New Jersey, under certain circumstances.

Jan Weinstock: I don't believe that's universal.

Audience Member 9: It's not.

Jan Weinstock: It's not universal in the states.

Audience Member 9: I think, it's a striking difference to take into account, the way in which we think about removing organs, and the way in which we think about having a coroner dissecting a body.

Jan Weinstock: Great point, yes.

Audience Member 10: But, I mean, not to draw out the discussion, but even in that circumstance, it's under certain circumstances, so if it's a suspicious death, obviously they're going to require the coroner to take a look, but there's even certain practices in which, they go about if there's a religious objection. I know for Jewish deceased individuals who have to have an autopsy they'll have the rabbi come in, and they have this tarp, and then they lay the body out, and they wrap everything out. There's mechanisms in a way to get around that but I mean its not as though it's an you know . . . .

Jan Weinstock: So one of the struggles when we talk about converting. I asked you the question in a vacuum as what should we do. Converting from one system to another is interesting and how one goes about the educational piece, so I do want to just finish this because I know you folks that have stayed with us for a while, and we appreciate that. So we're doing opt-out so let's assume we all supported opt out now, OK? So now we are on the next vote. If it's opt-out are you doing pure which is alright, I didn't opt-out so it doesn't matter what the family says or are you going to do soft where if the family voices an objection you will not recover the organs. Do you understand the two options? Okay.

Who is going for the pure opt out? Okay. Who is going with soft?

Great. So that was a little closer. For those who went with the soft, Brittany [Verga] you went with soft I think, what, why?

Brittany Verga: I guess because the family also has an interest at that point in the deceased individuals. It isn't their personal interest, but it is an interest nonetheless.

Jan Weinstock: Yeah so let me suggest this. Brittany approached the question as a law student. Okay, and we're having a health law symposium so that's terrific. One of the issues that we face, all three of us is, that outside this building when the world is dealing with this issue they are dealing with it as family members. So they are worried about what their family wants, they are concerned about their family's feelings, and they are talking about death as well which certainly has a lot of issues tied to it as well. So that was interesting sort of the fifty-fifty. Let's put that aside for a minute.

Okay. Incentives, alright. Who would go for some non-financial incentives, whether it's you know access to different places? Who would go for I get priority on the waiting list if I was prepared to be a donor? Who would support that, that Golden Rule? Okay. Who doesn't? You didn't vote you don't support it. Interesting, so I'm trying to remember how people voted before. Why wouldn't you guys just, if you don't mind, I mean we're here we're a small group so, why wouldn't you support the Golden Rule piece?

Audience Member 11: Mine's mostly on instinct I'm uncomfortable with the idea that, I guess I'm uncomfortable with the idea that those choices are left, and I know logically that they might be, but I don't really have a reason.

Jan Weinstock: Well you're position is currently consistent with the position of the United States so all of those experts who put together our allocation policies right now apparently have been listening to the two of you, so I don't want you to feel that you're isolated there. There are reasons. So part of that then, and it may be I mean it would be an interesting conversation sometime, whether part of it comes into then moving into this issue of who is really worthy, which Jan spoke about. Who is worthy of being, is that what you were thinking?

Audience Member 12: Well yea, I think it comes to do with a philosophy situation like hey why don't you map these people out and what they mean to the people around them.

Jan Weinstock: And how far are we going to extend that assessment.

Audience Member 12: Who is more valuable than the next person?

Jan Weinstock: So, and these are tough issues, and they are, I have to tell you, they are interesting issues, and they're great to sit and have a discussion about when you do a case study. And then they are terribly frightening issues when you know a person that they're being, you know when they are really faced with it, and that's why we then go back to our two opening speakers because it's about people. So you know it's great that you have given us the opportunity today to share our thoughts on this we very much appreciate you spending the afternoon with us. Please think about it. Please talk to people about it. And please remember ultimately this is about people helping other people. Yes?

Russ Jackson: If I may, while you're on a waiting list if you got priority or not doesn't mean you're gonna get that first organ that becomes available

Jan Weinstock: That's correct.

Russ Jackson: If it wasn't made for you, so that's a moot decision. Once your blood type matches, your size and everything else, let's say for a heart I can speak to that first hand. It has to fit. If it doesn't fit then, because I was number one on a list in New Jersey. I went in New York like 300 days, so then they put me on one in New Jersey but guess what, the guy in the bed next to me he got his before I did. So whatever situation, there can be no favoritism.

Jan Weinstock: Well I think the context this is being offered is if we have five individuals who are somewhat similar, similar blood type, similar size, and an organ was available what will we use to stratify that? Whose name is going to come up first and should there be any additional credit given for the fact that they were a donor? So that, I mean, I don't know if you folks have additional comments I'm finished my presentation I thank you for staying, and Brittany [Verga] was there anything else you wanted before we leave?

End of Symposium