

Testimony



**Testimony of William Minogue, M.D.
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 Transplant Consortium
 to the Senate Subcommittee on Investigations**

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Good morning Chairman Collins, Senator Levin, and Members of the Subcommittee. I am Dr. William Minogue, Chairman of the Board of Directors for the Washington Regional Transplant Consortium (WRTC). I would like to thank you for this opportunity to testify before the Subcommittee today on what I consider to be a very important issue. My goal is to share with the Subcommittee WRTC's experience with the tissue banking industry.

The WRTC

The Washington Regional Transplant Consortium is the federally designated organ procurement organization (OPO) for the Washington, D.C. area. We perform organ recovery services for 48 hospitals in Maryland, Virginia, and the District of Columbia, a responsibility we have held since 1988. As you are aware, all organ procurement agencies are required by federal law to be non-profit organizations. We are a non-profit organization under section 501c(3) of the federal tax code. Each OPO has regulated functions, responsibilities, and reimbursement practices. Each OPO has a Board of Directors or an advisory board with federally mandated representation requirements. WRTC's Board of Directors includes transplant surgeons, a liver transplant recipient, a donor family member and a prominent biomedical ethicist. I am an internist.

Federal law makes one OPO responsible for organ recovery and distribution for a given geographical area. Further, federal law makes the OPO responsible for approaching the family regarding the option of organ donation. This arrangement avoids the confusion and damage that may result from having several agencies competing for the attention and cooperation of the same valuable resource – people willing to donate organs. This same arrangement does not exist for tissue donation.

Although WRTC is not a tissue bank, in that it does not process

or distribute tissue, we are a tissue recovery agency. As such, we evaluate potential tissue donors, approach potential donor families regarding their donation options, and recover donated tissue. We are designated by nearly all the hospitals in the Washington, D.C. metropolitan area to recover donated tissue for transplant, research and/or medical therapies.

WRTC has chosen to offer organ and tissue recovery services for one purpose, to protect the integrity of both the organ and tissue donation process. WRTC has made this decision for a simple reason: to the public, organ and tissue donation constitutes the same activity. People, and particularly families confronting the loss of a loved one, do not see any distinction between a person who recovers a loved one's heart, lungs, liver or kidneys and the person or organization that recovers skin, bone and eyes. A poor experience with tissue donation has a direct and adverse impact on the ability of the WRTC to carry out its responsibilities to recover life-saving organs for transplant. The reality is that each time a family decides not to donate because of confusion or suspicion, then we risk the lives of several people waiting for organ transplants.

To ensure that people remain willing to donate, they must trust the donation system. The organ and tissue recovery process affects people when they are most vulnerable. This circumstance can easily give rise to misunderstanding, causing suspicions that their loved one is being nudged toward premature death so that organs and tissues can be taken for the benefit of others. The public must have every confidence that no one will directly profit from the death of their loved ones and that the donation system will work to protect them and their loved ones from abuse or misuse.

WRTC seeks to protect the integrity of the donation process by offering a single, non-profit donation resource for hospitals and families. We have one high standard for family approach, donor screening and organ and tissue recovery. Additionally, we have, through practice and experience, developed an approach to working with donor families that respects their grief, while offering them the possibility of turning their loss into some greater good.

Our goal is to ensure that all people who can donate are given that option and that both the donor and the donated gifts are treated with the respect that they deserve. We provide a valuable service to all members of our community: to the hospitals, to the

recipients and most importantly, to the donors and their families. We are responsible for the integrity of the organs and tissues that are recovered. We are entrusted with protecting the recipient community from potentially unsafe organs and tissue. Moreover, we are accountable to the donors and their families to ensure that these gifts will be respected and utilized appropriately. This includes an open and honest discussion with the donor family about the viable options for donation.

For this reason, we endorse the recommendations brought forth in the "Model Elements of Informed Consent for Organ and Tissue Donation" developed jointly by the Association of Organ Procurement Organizations, the American Association of Tissue Banks and the Eye Bank Association of America. We encourage its implementation industry-wide.

Organ versus Tissue Donation

Organ and tissue donation are different, both in the way they are regulated and in their clinical application. Organ donation is life-saving. However, donor organs are not readily available. There are over 75,000 people waiting nationwide for this life-saving gift. Tissue donation is life-enhancing and improves the quality of life. However, since there is no comparable shortage of tissue for donation, or urgency for tissue transplants, we impose stricter standards on tissue donor suitability. If tissue donor evaluation and recovery practices are unsafe, a recipient can be subjected to unnecessary risk. Tissue recipients must trust the recovery agency to ensure their safety. With non-profit organizations like WRTC, if a recovery places the potential recipient at risk, the recovery does not take place.

Organ donation procedures are comprehensively regulated while tissue donation is not. This absence of comprehensive regulation and oversight has caused significant difficulties, confusion, and standard variances for both organ and tissue donation because activities in tissue donation are integral with organ recovery activities and can directly impact organ donation. This, in part, is why we support the Food and Drug Administration's (FDA) proposed rules on donor suitability and good tissue practices.

An Example of Best Practices in Tissue Banking : LifeNet

WRTC has chosen LifeNet to process and distribute tissue recovered by WRTC. LifeNet is a federally designated OPO and a tissue bank fully accredited by the American Association of Tissue Banks. They are located in Virginia Beach, Virginia. We

have chosen to work with LifeNet because of their high standards and because LifeNet also recognizes that tissue banking and organ donation are inextricably linked. LifeNet shares WRTC's view that, in order to protect the nation's organ donation program, tissue donation must work in concert with organ donation when dealing with hospitals and approaching donor families. We trust LifeNet as our partner because of their integrity, their quality products and services, and their commitment to donors and their families.

An Example of Inferior Tissue Banking

Regrettably, not all organizations involved in recovery, processing and distribution of tissue share our concern to maintain and respect the integrity of the donation process and the sanctity of the donated gift.

Consider the following scenario. This is an account of an actual event that occurred right here in the Washington, D.C. area.

An elderly patient died at a local hospital. In accordance with the federal regulations, the hospital referred this case to the local OPO for potential donation. The OPO determined that this patient was not a candidate for organ or tissue donation and communicated this to the hospital and the family. This decision was based on the generally accepted suitability criteria from tissue banks. Some time later, the OPO received an excited call from the local hospital. The hospital demanded to know why this patient was now being pursued for tissue donation when the family had already been told that their loved one was not a candidate for donation.

The OPO investigated this case and determined the following:

Another tissue recovery agency obtained confidential patient information without the hospital's knowledge.

This second tissue recovery agency told the family that this tissue could be recovered for transplant purposes.

The family specifically stated that they did not wish tissue to be recovered for use in medical research. However, research donation was the only realistic donation option for a patient with this profile.

The second tissue recovery agency was pursuing the

tissue for transplant even though the following medical conditions existed and had caused the OPO to decline the tissue:

The patient was outside the generally accepted age range for donation.

The patient had a history of cancer that had rendered the tissue medically unsuitable for donation by the OPO standards.

The patient had been dead for almost 24 hours when the second tissue recovery agency contacted the family. Twenty-four hours following cardiac arrest is the generally accepted time frame inside of which the safe recovery of tissue for transplant can occur. Tissue should not be recovered after twenty-four hours have expired.

There was evidence of a recent infection affecting this patient.

The investigation points to the following conclusions:

A second tissue recovery agency inappropriately obtained the confidential patient information, without the hospital's knowledge or approval, and pursued the case for donation. The fact that the family had specifically stated that they did not wish to donate for research indicates that this agency was pursuing donation for transplant purposes or suggests that the agency was recovering tissue for research but not fully disclosing that intent to the family. The second tissue recovery agency was recovering tissue in our area for a publicly traded, for-profit, tissue bank. Neither the for-profit tissue bank nor their local recovery agency had a written agreement with the hospital to recover tissue at this facility, nor were they authorized to talk to the family about tissue donation options. The local OPO was not aware of any disclosure by this second tissue recovery agency to the hospital that they were pursuing this case for tissue donation. Finally, the second tissue recovery agency did not notify the local OPO of their intent to recover tissue from this patient.

The hospital staff and the donor family were confused by the actions of this second tissue agency. The family was upset that

they were subjected to conflicting and confusing information so soon after losing a loved one.

Situations like this occur when organizations that lack sufficient experience in tissue recovery and adequate regard for the donation process become involved in recovery. Furthermore, these organizations often operate from profit motives that supercede the public interest in donation. Our example illustrates, among other things, the importance of protecting donor families and patient confidentiality, as well as the necessity for clear industry standards with regards to the safety and soundness of the donated tissue. This disturbing donation event caused both the family and the donation process to suffer.

The Consequence of For-Profits in Tissue Donation

There are an increasing number of for-profit tissue processing and distribution agencies entering the donation arena. These entities need access to human tissue in order to generate revenue and are under shareholders' pressure to increase their market position to maximize profits. These organizations are not required to take the overall donation interests of the public into account and, unlike OPOs, their boards have no requirements to represent the public interest.

For-profit corporations influencing tissue donation practices hinder the overall organ and tissue donation process, and can bring about serious negative consequences. In our experience, the public interest is not being served by these developments.

We have seen a for-profit tissue bank tell hospitals in our area that there are genuine transplantable tissue recovery options outside the criteria used by the local OPO. The WRTC standards in donor screening ensure the maximum potential for tissue donation, while maintaining the safety of the donated tissue. This practice by for-profit tissue banks has caused confusion among local hospitals regarding suitable donation options.

We have seen a for-profit tissue bank engage in less than candid discussions with donor families regarding tissue donation options. We know that for-profit tissue banks working in our area have told donor families that tissue from loved ones over the age of 80 years old can be recovered for transplant. Tissue from these patients has a high likelihood of being

unsuitable for transplantation. Given the high probability that this tissue would not be used for transplant, a family that donates tissue could justifiably feel misled and abused once they learn that the tissue was not transplanted. The consequence of these types of donation events is a wholesale public distrust of organ and tissue donation.

We have seen a willingness by for-profit tissue banks to recover human tissues that are generally considered unsuitable for transplant. This raises concerns regarding recipient safety. As there is no shortage of human tissue for transplant, these types of recoveries constitute an unnecessary risk because they may produce sub-standard grafts and/or be at risk for infection or disease. A tissue bank's willingness to embrace this level of risk can be explained only by the tissue bank's need to increase corporate revenues and profits. Also, this need is not balanced by any countervailing obligation to serve and protect the public.

We have observed a for-profit tissue bank create non-profit recovery agencies or use local, non-profit organizations as a conduit for human tissue into their processing and distribution facility. These non-profit groups usually have established relationships with hospitals outside of tissue donation, which gives them access to hospital facilities and patient information. Patients and their families, as well as members of the local non-profit organization themselves, are not aware that the donated gifts will go to a publicly traded corporation as raw material. Unlike OPOs, these non-profit groups will not serve the public interest in donation, nor will they work to protect the public trust in organ and tissue donation. Instead, they will serve their for-profit tissue bank. A for-profit tissue bank is under no obligation to take the integrity of organ donation into account in the activities it promotes or sponsors.

A for-profit tissue bank increases its profits by the unrelenting pursuit of human tissue. In this case, this raw material is transplantable human tissue and those pursued are donor families. Under present conditions, we have seen donor families subjected to

pressures from various third party agencies with different agendas and approach strategies at a time when these families are most vulnerable and suffering great sorrow. We are losing our ability to offer the single, sensitive, compassionate approach that OPOs have refined over the years. Families are confused by multiple donation approaches and one can imagine a family's disgust over multiple agencies competing for their loved one's body parts. This situation, if allowed to continue, will undoubtedly cause a groundswell of negative feeling against organ and tissue donation.

We have experienced a third party tissue recovery agency responding to the tissue demands of its for-profit processor by recovering tissue from hospitals where it does not have a written agreement. This results in a third party entity gaining access to hospital facilities, patient information, and medical staff without the hospital's authorization or approval and then recovering tissue from a patient at that facility without the hospital's knowledge. These third party recovery agencies have also attempted to transfer bodies out of hospitals to locations such as funeral homes, where they are able to perform the recovery. This is all done without the knowledge of the local OPO. Hospitals hold the local OPO accountable for the quality of the donation activities. Yet, under the current system, the OPO is not always responsible for tissue donation actions. With several organizations recovering tissue from area hospitals, each using a different standard for family care and tissue recovery, both the donor and the recipient communities suffer.

In summary, WRTC has seen firsthand the adverse consequence of a for-profit sponsored tissue bank recently operating in our area. The testimony presented here today is a real account of our experiences over the past three years.

Recommendations

We strongly believe that both donors and recipients must be protected: the former by implementing an approach such as the "Model Elements of Informed Consent for Organ and Tissue Donation" and the latter by the swift adoption of the Food and

Drug Administration's two proposed rules on expanded donor screening and testing and on standards for good tissue donation practices. We also endorse instituting an annual reporting mechanism for all entities, for-profit and non-profit, involved in the tissue donation process to ensure transparency. We are pleased that tissue banks have begun registering with the FDA in accordance with its newly implemented rule, and hope that comprehensive inspection of all tissue banks by the FDA will soon follow. Moreover, we agree with recent actions taken by the FDA in urging a large tissue processing and distribution organization to stop its practice of pooling tissue from multiple donors during processing. The experience with Creutzfeldt-Jacob Disease (CJD)-contaminated dura mater allograft is adequate evidence of the need to ban the practice of pooling tissue. WRTC would like to highlight two additional recommendations for your consideration.

First, we recommend giving OPOs oversight authority over all donation activities, including family contact, donor evaluation, recovery, processing and distribution. We believe that this is essential to protecting the organ donor program and is critical for establishing mechanisms to uphold the public trust in organ and tissue donation, especially as the organ transplant waiting list continues to grow. This would enable OPOs to ensure that all participants in the tissue donation process are adhering to the highest standards.

Second, we recommend that all tissue recovery organizations be non-profit and that their relationships with for-profit corporations be strictly held at arm's length, free of monetary incentives and other forms of support. It is our hope that this will prevent for-profit organizations from pressuring non-profit companies to recover potentially unsafe tissues and to skirt the family approach protocols in an effort to increase recovery rates. It is neither wise, nor possible, to eliminate for-profit companies from all processing and distribution activities resulting from tissue donation. In fact, new patient care technologies, based on donated human tissue, may well be developed by for-profits or jointly between non-profit agencies and for-profit companies. However, for-profit organizations should not be involved, directly or indirectly, in the approach of donor families and the recovery of

donated tissue. This is essential to ensuring that the public is able to trust the donation program. Regulating the recovery of donated tissue, and insisting that this service is carried out by a non-profit organization under the direct control of the OPO, will make certain that the integrity of and trust in the donation process is maintained.

Conclusion

The public does not distinguish between organ donation and tissue donation. Organ donation is well-regulated and closely controlled in the public interest. The task before us now is to ensure that the tissue banking industry is held to the same high standards. This is particularly necessary in order to protect organ donation. The actions of one unscrupulous tissue bank can adversely affect both organ and tissue donation. Any reduction in organ donation means the loss of life. We are already seeing instances of this reaction when, for example, in a hospital in Florida, the reported activities of a local tissue bank caused a family to decline their option of organ donation. This is the single greatest threat to the growing list of 75,000 individuals awaiting organ transplant in this country. Moreover, quality donated tissue transplants greatly improve the lives of countless numbers of people every day.

We must ensure that both the recipient and the donor communities are well served. We must work to advance the public perception of the organ and tissue recovery process, and bring this process to a point where it is understood and trusted. We look forward to the day when the general public completely accepts the benefits of organ and tissue donation as a common, dignified, and valuable contribution to the quality of life and of death.

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