



Changing Lives
Through Tissue Donation

State of Wisconsin Legislative Council
Special Committee on Powers and Duties of Coroners and Medical Examiners

September 28, 2005

Dear Committee Members:

On behalf of the Musculoskeletal Transplant Foundation (MTF), I would like to thank you for the time and dedication you are putting into the process for reviewing the powers and duties of the Wisconsin coroners and medical examiners. Over the years, MTF has worked diligently to build positive relationships with coroners and medical examiners throughout the state in offering the option of tissue donation to families in times of crisis.

Historically, we have been fortunate to experience good working relationships with coroners and medical examiners, and appreciate their willingness to work cooperatively with us to promote donation in their communities.

However, as of late, we have been troubled by a movement within the coroner/medical examiner community to work with a tissue bank that does not have a history of providing tissue back to the state for transplant. We are concerned that coroners' offices are entering into tissue recovery arrangements with **little regard for local communities' needs** for tissue grafts. Also, that the process for selecting a tissue recovery agency for these counties has been a closed process, unilaterally made by the coroner that does not openly evaluate the services of all Wisconsin tissue recovery organizations.

We want to bring to your attention that MTF provides a tremendous amount of tissue for transplant to the residents of Wisconsin. Last year alone, over **5,000 MTF tissue grafts** were transplanted into patients around the state. Tissue for transplantation is a scarce community resource, and the only way we can continue to provide this resource back to your communities is when we are able to participate in the donor recovery process. When the coroners' or medical examiners' office re-directs donors to another tissue bank, the patients in your local communities suffer as the local hospitals do not have access to the tissue grafts for surgical procedures and donor families are denied the opportunity to help others in their community through their loved one's gift of tissue donation.

MTF respectfully asks the special committee to consider two issues related to tissue donation.

First, we want to clarify that there are no local, state or federal guidelines addressing the referral of non-hospital deaths for tissue donation. If any county coroner or medical examiner is pursuing a relationship with a tissue bank for non-hospital deaths, we ask that this process be open and fair. It is our position the counties should conduct a **public selection process** whereby all tissue banks that serve Wisconsin have an opportunity to respond to a Request for Proposal from the county for tissue recovery services, and be evaluated using objective screening criteria. MTF believes the **criteria** should include the following:

- **Accreditation Status:** The American Association of Tissue Banks (AATB) sets standards for tissue banks, and accredits tissue banks throughout the country. A county faces serious risk management issues if it is working with a non-AATB accredited tissue bank, as the county has no assurance that the tissue bank is abiding by a set of minimum standards.
- **Food and Drug Administration (FDA) Registration:** All tissue banks are required to register with the FDA within five days of initiation of operations. Tissue Banks should show evidence of FDA registration.
- **Non-Profit or For-Profit Status:** A county should review the status of the tissue bank and determine if the organization is a 501(c)3 non-profit, charitable organization, or that the tissue bank has a mechanism for processing tissues with a non-profit tissue processor.
- **Tissue for Transplant:** A county should review the number and type of tissue grafts a tissue bank provides back to the community. This information is readily available as tissue banks are required by the FDA to track tissue. Since tissue donation is a community resource like blood or organ donation, we believe the county should give strong consideration to this criterion. Families deciding to donate their loved one's tissue to help a neighbor at the most difficult time in their lives is the essence of donation and the spirit of giving that motivates many of these remarkable donors and their families.

Second, MTF asks you to recommend that coroner's and medical examiner's offices **adhere to the tissue donation agreements that hospitals** currently have in place for in-hospital deaths. Hospitals pursue a thorough process for selecting an organization to provide tissue donation services to their patients. All donation agencies that have agreements to serve a particular hospital have inter-related processes which have been implemented to minimize the impact of the donation on the donor family. Additionally, according to Federal Regulation 42 CFR 482 (a) (1) and (2) the hospital is required to have an agreement with at least one tissue bank and the hospital must have arrangements to offer suitable donor families the opportunity for donation.

In several instances, a coroner or medical examiner is involved with an in-hospital death, and, lately, several coroners' offices have been re-directing donations away from the tissue bank contracted with a hospital. When the coroner or medical re-directs a donation to another agency not contracted with the hospital, the donation processes are severely interrupted causing much confusion to the hospital staff and the donor family. Also,

these re-directions may cause the **hospital to be out of compliance** with Federal Regulation 42 CFR 482 (a) (1) and (2). Again, MTF believes the coroners and medical examiners should honor the hospital agreements for tissue donation.

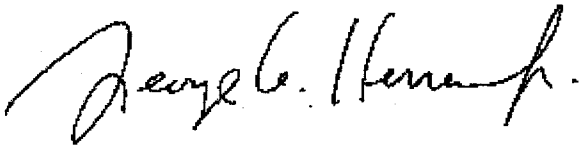
The Centers for Medicare and Medicaid Services (CMS) has sent two letters to coroners that clearly illustrate this Federal Agency's concern and guidance regarding these practices. It is our understanding one of these letters has already been provided to the Committee for review.

The coroners and medical examiners in the state of Wisconsin have a history of supporting both organ and tissue donation, and we hope this support will continue. We believe the selection process for a county-based agreement for tissue services should be an open and public process, and the hospital tissue donation agreements should be honored.

MTF is committed to providing this Special Committee with all information related to understanding the critical link between the gift of a donor and their family and the availability of safe and transplantable tissue for the benefit of patients in Wisconsin. If you have any questions or if I can be of assistance to the Special Committee in addressing these concerns, please contact me directly at 281-320-9919 or george_herrera@mtf.org.

We look forward to discussing these issues, and working with you to make Wisconsin a leader in donation. Together we can provide our citizens with the transplant resources that they so greatly need.

Sincerely,

A handwritten signature in black ink that reads "George A. Herrera". The signature is fluid and cursive, with a large initial "G" and a long, sweeping tail.

George A. Herrera
Vice President, Donor Services
Musculoskeletal Transplant Foundation

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