Testimony

Testimony of Valerie J. Rao, M.D.
Chief Medical Examiner, District Five, Leesburg, Florida
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Good morning Chairman Collins, Senator Levin, and Members of the Permanent Subcommittee on Investigations. My name is Dr. Valerie Rao, and I am the Chief Medical Examiner for District Five in the State of Florida. I would like to thank you for inviting me to appear today before the Subcommittee and I am pleased to discuss this most important issue. I believe that human donation is a selfless and invaluable gift, and as such, would like to see that all tissue recovery organizations are required to adhere to standards that promote safety and respect for donation. Unfortunately, my observations tell a different story and I would like to share my experience with the Subcommittee.

The role of the medical examiner in organ and tissue transplantation programs results from government mandated investigation into sudden and unexpected or traumatic deaths to determine the cause and manner (natural, accident, suicide, or homicide). A medical examiner death investigation includes documenting and evaluating the scene of death or injury as well as the body at the scene. Included is the determination of the terminal episode history and the decedent's medical history.

In Miami-Dade County, where I spent 18 years and nine months as an associate medical examiner, when a case arrives, it is initially screened by a tissue bank coordinator for consideration as a potential donor. If the quality appears suitable, next-of-kin authorization is received. In the meantime, the medical examiner performs a careful external examination. Next, the body is transported to a sterile autopsy suite where a tissue bank pathologist participates in the tissue excision process. During this procedure blood and lymph node tissue are retained for screening. The body returns to the medical examiner and the tissue bank pathologist. For the non-medical examiner case, the tissue bank pathologist performs the autopsy. At any time during this procedure, should testing raise doubt, the donor

material is removed from the preparation and distribution pipeline.

Most medical examiner donor cases are people of prior good health who experience violence 24%, of sudden, unexpected, noninfectious cardiac dyshythmia, or stroke, 76% (Statistics in Miami-Dade County, Florida 1995 through 1999). The very nature of such cases of previously healthy individuals with sudden death, creates a donor pool where infection and malignancy are minimize.

The protection against transmittal of infection and malignancies must be the primary principle in all transplantation programs; and the shortage of donor materials and business pressures should not work against this principle. Therefore, it is recommended that tissue bank physicians and coordinators become aware of their own state medical examiner guidelines in order to understand the investigative process and its relationship to quality assurance.

As the medical examiner determines the cause of death, a complete autopsy and tissue for subsequent microscopic examination serve as a quality assurance step in the transplant process. Medical examiners are charged, in addition to forensic investigations of death also with public health issues particularly with regard to the possibility of transmission of infectious disease. Autopsies are required for donor acceptance, and medical examiners believe that autopsies should be routine for all donor cases. Autopsies are the only means by which diseases such as tuberculosis, histoplasmosis, degenerative disease of the brain, unsuspected malignancies, viral myocarditis, non-A, B, or C Hepatitis, diseases of unknown etiologies, and other potential transmissible diseases can be detected and those donors excluded from the donor pool.

The entire issue of medical examiner participation in the acquisition of tissues from cadaver donors must be also considered in light of recent developments. As I stated, medical examiners are guardians of the public health interest, and should be in a position to make a determination which tissue bank serves both the interests of the recipient-patient as well as satisfy the medical examiner statutory duties. Certainly a trust in the professional competence and reputation of the tissue bank personnel is an important factor in making such a

determination.

Last April, I became concerned regarding several questionable practices by a tissue bank. My first concern, was when Regeneration Technologies, Inc., through its association with the University of Florida Tissue Bank, would accept donors with non-metastasizing malignant tumors of the breast, colon, cervix, and lung. They also accepted donors with septicemia, pneumonia, and intestinal obstruction. To the best of my knowledge, they do not perform routine blood or bone marrow aspiration cultures, which is done to detect for possible diseases. They do not require an autopsy, and hence do not know the cause of death in the donor. Tissue excisions are performed by technicians without physician supervision or participation; and the use of sterile precautions are not observed during the excision and retrieval processes. The technicians do not have sufficient training and knowledge to observe changes which would be noted by a pathologist, yet they performed an autopsy-removal of the brain which would obviously impair further medico legal investigation of the body of the deceased. Finally, the customary care and respect for the body of the deceased are not observed. I believe, the dead have rights, too! In contrast, the University of Miami Tissue Bank has demonstrated quite the opposite: all of their excisions are performed asceptically by trained physicians in an operating room environment; blood cultures and bone marrow cultures are also routinely performed.

As I said before, I believe that public trust in the professional competence and reputations of those involved in the donation process is vital to its continued success.