



NJ SHARING NETWORK TALKING POINTS INVESTIGATION OF BIOMEDICAL TISSUE SERVICES JANUARY 12, 2006

Background:

In October, newspapers in New York and New Jersey carried the story of a New York investigation into “illegal recovery” of tissues from deceased individuals at funeral homes in New York. The investigation focused on Biomedical Tissue Services Ltd., (BTS) a Fort Lee, N.J., for-profit tissue Recovery Company, which allegedly recovered tissues from the New York area funeral homes. Since that time we have learned that BTS is under investigation for allegedly falsifying donor records, including consent forms. As a result of these allegations, all the tissue recovered by BTS and sent to accredited facilities for processing has been voluntarily quarantined or recalled. The following questions and answers are designed to provide additional information about this incident and its impact on NJ Sharing Network.

What happened?

If the allegations are true, deceased individuals were removed from funeral homes, or recovered in funeral homes without consent and taken to a facility where the tissue was recovered and distributed to legitimate tissue banks.

How did this happen?

If the allegations are true, there were criminal activities—forging signatures, falsifying consent to donate, falsifying medical records, etc.—that resulted in the distribution of unscreened donors and tissue.

Is NJ Sharing Network involved in the BTS incident?

NJ Sharing Network **is not involved** in this investigation nor did we know anything about it until the story broke in the press. We do not recover organs or tissue at funeral homes.

What is NJ Sharing Network’s relationship with LifeCell, which received some of the tissue recovered by BTS?

Consistent with our desire to maximize use of donations, NJ Sharing Network has a working relationship with LifeCell. We learned that LifeCell discovered discrepancies in the business practices of BTS and discontinued their relationship with them on September 30th. LifeCell is cooperating fully in all investigations.

Unlike donated organs, which go directly to people on the waiting list, tissue donation requires us to form partnerships with organizations which process and distribute the various forms of donated tissue we recover. For this reason, NJ Sharing Network gives extreme scrutiny to these partnerships and we will only select those that reflect the same commitment to our donors and

New Jersey Organ and Tissue Sharing Network, Inc.
841 Mountain Avenue • Springfield, NJ 07081
973-379-4535 • www.sharenj.org
Fax (general): 973-379-5113 • Fax (clinical): 973-379-4311 • Fax (laboratory): 973-379-3719





their families as we do. Our affiliations are evaluated regularly to ensure all of our partners maintain the highest standards for safety, ethics and industry practices.

Is there any government oversight of this process?

Tissue banks are regulated by the FDA. As a result of these allegations, the FDA has instructed tissue banks that distributed any tissue recovered by BTS to contact the implanting physician. The FDA and CDC recommend that transplant surgeons advise their patients that they received tissue from a donor for whom an adequate donor eligibility determination may not have been performed. Because of liability concerns, some hospitals are also notifying patients.

How does NJ Sharing Network protect transplant recipients against receiving contaminated or “stolen” tissue?

We do not recover organs or tissue at funeral homes--all of our potential donors come from hospitals. We adhere to a very strict protocol to receive consent for donation. In addition the Network conducts a thorough medical and social history of all potential donors before recovering any tissue. All donor families receive a copy of the consent form as a confirmation of their consent to donate. Organ donor blood is tested for infectious diseases prior to the recovery of the organs. If a serious communicable disease is identified in the donor, the recovery does not proceed. The blood of tissue donors is also tested for infectious disease before the tissue is processed or released for use in patients. Organ recoveries are done in sterile operating rooms and tissue recoveries (in cases where no organs are being recovered) are done in a sterile facility designated specifically for this purpose. NJ Sharing Network works with tissue banks that follow standards and regulations for ethical and legal treatment of donors and anatomic gifts set forth by federal and state laws and regulations and government agencies such as the Federal Food and Drug Administration, New Jersey Department of Health and Senior Services and the American Association of Tissue Banks (AATB.)

Statements have appeared in press reports that recipients may have received “diseased implants.” There have also been isolated reports in the media that tissue recipients have “tested positive for hepatitis and syphilis.” To date, the AATB has received **no confirmed reports** of any adverse events related to tissue that was retrieved by BTS and processed by AATB-accredited banks. Because of the stringent screening, testing and processing standards of AATB-accredited banks; it is believed that any risk to patients is extremely low. Until investigations are completed for each case, it is unknown if the tissue in question was retrieved by BTS, if the individuals involved had risk factors, or if they could also have tested positive before their surgery. In light of these events, the AATB has formed a task force to determine if any changes in standards are needed to help guard against the falsification of donor and medical records.

This is an investigation of criminal activity, it is not the norm. NJ Sharing Network urges everyone to remember the value of organ and tissue donation and how transplantation of donated tissue can significantly enhance the quality of life for many individuals. Those individuals considering a tissue transplant, should discuss the details with their physician.

New Jersey Organ and Tissue Sharing Network, Inc.
841 Mountain Avenue • Springfield, NJ 07081
973-379-4535 • www.sharenj.org
Fax (general): 973-379-5113 • Fax (clinical): 973-379-4311 • Fax (laboratory): 973-379-3719





NJ Sharing Network encourages anyone considering tissue donation, to do so, as donation is one of the most precious gifts that can be given.

New Jersey Organ and Tissue Sharing Network, Inc.
841 Mountain Avenue • Springfield, NJ 07081
973-379-4535 • www.sharenj.org
Fax (general): 973-379-5113 • Fax (clinical): 973-379-4311 • Fax (laboratory): 973-379-3719

