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IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CRIMINAL TRIAL DIVISION

ACTIVE CRIMINAL RECORDS
CRIMINAL MOTION COURT

IN RE : MISC. NO. 05-011487
COUNTY INVESTIGATING :
GRAND JURY XXI : C-10

REPORT OF THE GRAND JURY

LYNNE ABRAHAM
District Attorney

IN THE COURT OF COMMON PLEAS OF PHILDELPHIA COUNTY

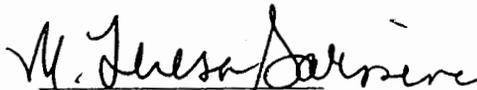
TRIAL DIVISION

IN RE : MISC. NO. 05-011487
COUNTY INVESTIGATING :
GRAND JURY XXI : C-10

FINDINGS AND ORDER

AND NOW, this 27th day of September, 2007, after having examined the Report and Records of the County Investigating Grand jury XXI, this Court finds that the Report is within the authority of the Investigating Grand Jury and is otherwise in accordance with the provisions of the Investigating Grand Jury Act, 42 Pa.C.S.A. §4541, et. seq. In view of these findings, the Court hereby accepts the Report and orders it sealed until further order of the Court. At that time, the Report shall be unsealed and the Court will refer it to the Clerk of Court for filing as a public record.

BY THE COURT:


M. TERESA SARMINA
Supervising Judge
Court of Common Pleas

I HEREBY CERTIFY this foregoing to be
a true and correct copy of the original
Findings & Order as filed in this
office.

Date: 9-29-07


Active Criminal Records
Original Motion Court Clerk
Street Judicial District

**IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CRIMINAL TRIAL DIVISION**

IN RE : **MISC. NO. 05-011487**
COUNTY INVESTIGATING :
GRAND JURY XXI : **C-10**

REPORT

TO THE HONORABLE M. TERESA SARMINA, SUPERVISING JUDGE:

We, the County Investigating Grand Jury XXI, were impaneled pursuant to the Investigating Grand Jury Act, 42 Pa.C.S.A. §4541 et seq., and were charged to investigate an alleged body harvesting scheme in which three Philadelphia funeral directors who owned a crematory conspired with operators of a tissue recovery business to steal body parts and sell them for transplantation based on fraudulent and forged documents. Having obtained knowledge of such matters from physical evidence presented and witnesses sworn by the Court and testifying before us, upon our respective oaths, not fewer than twelve concurring, do hereby submit this Report to the Court.

Foreperson

**IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CRIMINAL TRIAL DIVISION**

IN RE : MISC. NO. 05-011487
COUNTY INVESTIGATING :
GRAND JURY XXI : C-10

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INTRODUCTION

There is no nobler act at the end of one's life than making the decision to become an organ or tissue donor. It is the ultimate expression of brotherly love among human beings. Not only does contributing one's tissues give the gift of life to those in dire need, but it also provides solace, a sense of purpose, and dignity to those struggling to cope with the loss of loved ones. Donating body parts, however, is one thing: stealing from the dead is quite another. Sadly, this Grand Jury finds that a conspiracy of unscrupulous funeral directors and former medical workers took businesses normally associated with compassion and caring and perverted them into something ghoulish, greedy, dangerous, and criminal.

These predatory businessmen used their funeral homes and medical companies to traffic in stolen body parts with but one aim: to illegally enrich themselves. For them, nothing was beyond the pale – not stealing flesh and bones from the dead or lying to the bereaved, not forging and lying on thousands of documents, not putting the public's health at risk. First, without obtaining families' consent, the conspirators pilfered bones, skin, tendons, spines, and other tissue from bodies entrusted to Philadelphia funeral homes for cremation and burial. Then they compounded this fraud by criminally evading regulations and procedures designed to ensure the safety of body parts.

The tissue ultimately was used for what should be life-enhancing medical procedures – to heal burns, for instance, or replace worn or broken bones, or repair torn tendons. As a result, the conspirators endangered thousands of people nationwide who may have received tissue from cadavers that were infected with HIV, hepatitis, sepsis,

and other potentially deadly contagions. Not only did these traffickers in flesh and bones violate numerous laws, but they also cruelly stole from the families of those whose bodies were desecrated the comfort of knowing that loved ones were properly honored in their death and that the ashes retained or buried are even their remains.

This report will relate the story of one funeral home client to illustrate the way in which the cynical funeral directors, who are supposed to comfort and assist grieving family members, instead secretly conspired with thieves who slashed tissue from the cadavers, no matter if they were decayed or diseased. The story will also illustrate the means by which the conspirators then fraudulently handled, disguised, and sold the stolen tissue, which was later implanted into unsuspecting medical patients who were often desperately hopeful and needy.

The report will then examine the full scope of the criminal enterprise:

- How funeral directors Louis Garzone, Gerald Garzone, and James McCafferty used their Philadelphia funeral and crematory businesses to illegally procure thousands of body parts from the dead entrusted to their care between February 2004 and September 2005.
- How they permitted Michael Mastromarino, a disgraced former dentist, and his teams of so-called “cutters,” led by his right-hand man, Lee Cruceta, to eviscerate bodies awaiting cremation – hacking, sawing, dismembering, and taking anything they wanted – in an unsanitary embalming room described by one of the cutters as “like the back of a butcher shop.”
- How records from Mastromarino’s company, Biomedical Tissue Services, Inc. (BTS), show that his teams took tissue from a total of 1,077 bodies in

three states – Pennsylvania, New Jersey, and New York – including, without consent, from 244 bodies in the Philadelphia funeral homes.

- How bodies at the funeral homes routinely sat for days without refrigeration, sometimes in an alley or a garage, before Mastromarino’s cutters “harvested” the tissue. (One corpse sat for 113 hours after death, another for 100 hours. Safe tissue protocols require harvesting within 15 hours of death.)
- How one Philadelphia man’s body was harvested for parts the day *after* his funeral service was held. Another grieving family gathered to celebrate the life of the deceased at the precise time the cutters were stealing their loved one’s tissue.
- How Mastromarino and Cruceta, under the guise of a legitimate tissue procurement company, falsified records in order to sell the tissue that was illegally taken, often from diseased and decaying bodies, to companies that then distributed it to hospitals worldwide for use in medical procedures.
- How blood samples were deliberately mislabeled, resulting in tissue from bodies with HIV and hepatitis C evading tests designed to screen for these diseases.
- How the Garzones and McCafferty were paid approximately \$250,000 over an 18-month period for their participation in the criminal scheme to steal and sell body parts.
- How the Garzones and McCafferty further defrauded their customers and the Pennsylvania Department of Welfare by double-charging for their services and forging and falsifying public records.

- How BTS, Mastromarino, and Cruceta were paid more than \$1 million for tissue purloined from deceased Philadelphians during the 18 months they operated in the city. This was part of \$3.8 million in illegal profits they took in from New York, New Jersey, and Pennsylvania during this same period.
- How, in nearly half of the Philadelphia cases where the cause of death is known, the death certificate indicated that the people whose tissues were stolen died of cancer or sepsis, or were infected with HIV or hepatitis.
- How at least four companies distributed for implantation thousands of pieces of BTS tissue, some of it from infected corpses, all of it dangerously mishandled and mislabeled. (One company alone sold more than 2,000 pieces of tissue stolen from bodies at the Garzones' Philadelphia funeral homes; at least 5 Philadelphia-area and 41 Pennsylvania hospitals implanted BTS tissue in patients.)

The Grand Jury will describe how this scheme was finally uncovered by a New York police detective, rather than by those who are supposed to monitor funeral home activities and tissue procurement. The report will conclude that these crimes went undetected because current regulations and overseers fail to take into account the enormous incentives and opportunities to commit theft and fraud in the body tissue industry. Finally, the Grand Jury will propose actions that it believes will help prevent this travesty from recurring. Our recommendations are to:

- Prosecute to the fullest extent possible Louis Garzone, Gerald Garzone, James McCafferty, Michael Mastromarino, Lee Cruceta, and the corporations, Garzone Funeral Home, Inc. and Liberty Cremation, Inc.

- Prohibit funeral homes from performing tissue recovery.
- Make theft of body parts a distinct felony crime.
- Require all tissue agencies to be licensed by the state and accredited by the American Association of Tissue Banks.
- Strengthen auditing practices of those responsible for overseeing tissue agencies.
- Consider requiring that all tissue recovery be coordinated through one designated organization.
- Define “reasonable costs” that tissue banks are permitted to charge without violating prohibitions against buying and selling human tissue.
- Review policies that have permitted Louis and Gerald Garzone to continue operating their funeral homes.
- Improve oversight of funeral homes to serve the public’s welfare.
- Begin regulating crematories in Pennsylvania.
- Amend procedures for requesting and granting burial payments for welfare recipients.

THE REMAINS OF JOSEPH PACE

Joseph Pace was a widower who lived alone in the Kensington neighborhood of Philadelphia. He had worked for the Philadelphia Water Company as a supervisor at one time, but when he died on January 25, 2005, he had not worked for 15 years. His stepdaughter, Carolyn Garcia, testified that Pace had had to quit because of illnesses. His official death certificate listed his causes of death as: “cardio respiratory failure, sepsis, acute colitis, abdominal obstruction.” In addition, the death certificate noted cancer of the larynx, HIV sero positive, and hepatitis C as “other significant conditions contributing to death.” Pace died at 3:48 AM at Northeastern Hospital in Philadelphia. He was 54 years old. (*See appendix for documents relating to Joseph Pace.*)

Garcia told the Grand Jury that Louis Garzone had buried her mother in 1998, and so she went to him when her stepfather died. She made arrangements with the funeral director for a simple cremation, and she compensated him handsomely for it – paying him \$3,160. For this sum, Louis Garzone should have provided superlative care and service. But Garzone had other plans. For nearly a year, he had been part of a criminal plot to steal and sell body parts. The conspiracy included his brother, Gerald Garzone; their partner in a crematory business, James McCafferty; and a company founded by a disgraced former dentist from New Jersey, Michael Mastromarino, whose license had been stripped following his arrest on drug charges.

Louis Garzone did not respectfully prepare Pace’s body for cremation and burial. Instead, without informing Garcia or seeking her consent, the funeral director used Pace’s diseased corpse to make even more money. He accepted \$1,000 from Mastromarino to

allow a team of “cutters” into his funeral home to hack whatever tissue they wanted from the cadaver so it could be fraudulently sold to tissue banks. Garzone did this even though Pace’s death certificate clearly showed that his body was riddled with several deadly and contagious diseases – any one of which made his tissue unsuitable for transplantation.

At 7:55 AM on January 27, Lee Cruceta, the designated “team leader,” and his assistants, Kirssy Knapp and Richard Bifone, proceeded to cut up Pace’s body. They performed their cutting on a rusted table in a cramped, filthy, blood-encrusted embalming room in Louis Garzone’s funeral home on Somerset Street in Philadelphia. Within an hour, they had sawed off Pace’s arms and legs and stripped the bones from them. They had extracted other bone material, called cancellous bone, and had cut out his Achilles tendons. They had even sliced Pace’s skin off his body.

When they were done, the cutters stuffed into a body bag what was left of his torso, making no effort to put it back together. Louis Garzone would deal with the remains – and hide the evidence of their larcenous desecration – at Liberty Crematory, across the street from his funeral home.

Mastromarino’s team, meanwhile, placed the stolen body parts in coolers and drove them back to the headquarters of his company, Biomedical Tissue Services, Inc., (BTS) in Fort Lee, New Jersey. BTS subsequently sold Pace’s bones and attached ligaments and tendons to a company in Alachua, Florida, Regeneration Technologies, Inc. (RTI), for \$5,650. It sold Pace’s skin to LifeCell Corporation (LifeCell) in Branchburg, New Jersey, for \$2,364.

Mastromarino was able to find buyers for Pace’s diseased tissue by lying and falsifying documents to evade safeguards that are intended to protect the public from

defective and infectious implants. Indeed, on the records submitted by BTS to RTI, which are supposed to document the health history and condition of the person from whom the tissue was removed, there was very little that was true.

On these documents, Mastromarino falsified Pace's birth date and social security number. More important, on a form entitled "Certifying Physician Interview," he claimed to have interviewed Pace's doctor, "Dr. Hixson" – a physician that Pace's stepdaughter testified she had never heard of. Mastromarino represented on the form that the fictitious Dr. Hixson had seen Pace in the doctor's office a year earlier. The phantom doctor allegedly certified that Pace had no known history of HIV, hepatitis, cancer, or severe chronic infections. Other comments supposedly made by the "doctor" are scrawled and illegible, except the parts saying "no jaundice, or flu-like symptoms . . . no risk factors for communicable diseases . . . no contra-indications to recover tissue." The form is signed by "Dr. M. Mastromarino."

Pace had been dead – his body left sitting out, unrefrigerated – for more than 52 hours when Cruceta's team began to hack out his body parts. Standard safety protocols and BTS's contract with RTI required that tissue be harvested within 15 hours of death (or 24 hours if refrigerated). This posed no problem for Mastromarino, however. He simply claimed in the paperwork that Pace had died at 1:30 PM on January 26 – nearly 34 hours later than he actually died. The documents also claimed falsely that the body was refrigerated, even though Louis Garzone's funeral home had no refrigeration facilities.

Attached to the BTS paperwork was a "consent form" claiming to represent the consent given by "Linda Pace," purported to be Joseph Pace's wife. Carolyn Garcia,

however, testified that there was no such person. This form stated that the (fictional) spouse granted permission by telephone to cull Pace's body parts. Mastromarino and one of the cutters, Richard Bifone, signed as witnesses to the consent.

Also attached to the paperwork was a serology report on a blood sample that BTS submitted to RTI as Pace's. Before accepting tissue destined for transplantation, RTI conducts tests on blood that is supposed to come from the tissue donor. The blood is screened for HIV, hepatitis, syphilis, and other diseases that could make the tissue dangerous to implant. Pace's blood would have tested positive for both HIV and hepatitis C. Yet the serology report on the sample submitted by Lee Cruceta as coming from Pace's body reflects "negative" findings (that is, no disease was detected) for HIV and hepatitis. Caroline Hartill, RTI's vice president for Quality Assurance and Regulatory Affairs, was asked about these results. She testified that it was "highly likely that the blood that was provided – that was purported to be from Mr. Pace – was not from Mr. Pace."

The last document attached to the BTS paperwork was a phony death certificate, only partially filled out. Typed on it were Pace's name, the incorrect birth date, the incorrect social security number, and the incorrect time of death. An illegible signature, purportedly a doctor's, "certifies" the death and is accompanied by a fabricated medical license number. The causes of death listed do not include sepsis, or cancer, or HIV, or hepatitis, or anything else from Pace's official death certificate. Instead, the listed causes are ones that would not prompt tissue banks to reject Pace's body parts: "Acute Myocardial Infarction, Coronary Artery Disease, and Hypertension." Most of the "death certificate" is blank. There is no seal to certify authenticity.

Based on this totally fraudulent set of paperwork, Pace's infected tissue was purchased by RTI and LifeCell for distribution and implantation. (Records provided by RTI indicate that luckily – in contrast with the vast majority of body parts distributed by BTS – none of the tissue that RTI received from Pace was ultimately implanted. It is not known whether LifeCell distributed any of his tissue for implantation because the tissue bank did not comply with the Grand Jury's subpoena.)

Louis Garzone, meanwhile, did not limit the illegal gains he earned off of Joseph Pace to the payment he received from Mastromarino for the stolen tissue. Documents found in the funeral director's records show that he prepared at least two different bills for Pace's funeral. Even though Pace received a simple cremation, with no other services, Garzone's invoices fraudulently include items that he never provided. One bill, for \$3,160, includes a casket and embalming. Another, for \$8,700, includes charges for a viewing, embalming, a \$3,007 wooden casket, a luncheon, and \$1,750 for "professional services." Copies of checks drawn on Pace's bank account were found in the funeral home's files. The Grand Jury found that Louis Garzone, his brother Gerald, and their crematory partner, James McCafferty often used the bodies brought to them for funeral services to commit similar kinds of fraud.

THE CRIMINAL SCHEME

Documents reviewed by the Grand Jury show that the scenario revealed in Joseph Pace's story was repeated, with only slight deviations, on 244 bodies entrusted to Louis Garzone, Gerald Garzone, James McCafferty, their funeral homes, and their crematory, Liberty Cremation, between February 2004 and September 2005. In most cases, however, Michael Mastromarino's documents for Biomedical Tissue Services (BTS) falsify even the name of the dead person whose body was torn apart, so that their identity could not be determined. Investigators with the Philadelphia District Attorney's office were able to identify 48 of the 244 Philadelphia bodies from their death certificates. In addition to the illegal theft and fraudulent sale of body tissue, the Grand Jury has found 112 cases in which the Garzones and McCafferty defrauded clients and the Pennsylvania Department of Public Welfare by double charging for funerals, often forging their clients' signatures.

The Grand Jury's findings concerning how the funeral directors and their BTS partners conducted their criminal enterprise are based on several sources. We heard direct testimony from family members of those whose bodies were dismembered and parts stolen. We also heard statements and testimony from individuals who worked for the Garzones and Mastromarino and had first-hand knowledge of their operations. We heard the testimony of investigators who work for the federal Food and Drug Administration, Pennsylvania's Department of State, the Philadelphia District Attorney's office, and the Pennsylvania Office of Inspector General. We heard from experts who testified about, among other things, death certificates, crematories, welfare department procedures, and legitimate tissue businesses. We heard testimony from companies that purchased tissue

from BTS. We subpoenaed bank records for the Garzones, McCafferty, and BTS. And we reviewed thousands of pages of documents, including those that BTS distributed along with the tissue that it sold, as well as records provided by companies that bought the tissue.

What we found was appalling.

The Conspirators

Louis Garzone, Gerald Garzone, and James McCafferty each operated separate funeral homes and were also partners in a crematory business: Liberty Cremation, Inc. Louis Garzone's funeral home (named Louis Garzone Funeral Home, but incorporated as "Garzone Funeral Home, Inc.") was located at 1830 E. Somerset Street, in the Kensington section of Philadelphia. Louis's brother, Gerald, owned a funeral home, licensed in June 2005 under the name "Garzone Funeral Home," at 4151 L Street in Philadelphia. James McCafferty is the funeral director at his mother's business, James A. McCafferty Funeral Home, at 6711 Frankford Ave. The three funeral directors co-own Liberty Crematory, which is across the street from Louis's funeral home.

Michael Mastromarino was the founder and president of Biomedical Tissue Services, Inc., a corporation that he ran from its start as a criminal enterprise. Mastromarino was originally a dentist; he started the body harvesting operation in 2002, after he was stripped of his dentistry license because of drug abuse charges. (Despite no longer being a licensed dentist – and never an M.D. – he signed his name on tissue recovery documents as Dr. M. Mastromarino, sometimes adding "M.D.")

In the beginning, Mastromarino partnered with a funeral director in the Bronx, New York, and called his business BioTissue Technologies. When that partnership ended, he sought out new funeral homes to partner with in order to procure a supply of bodies. Mastromarino was working with a few funeral homes in New Jersey and New York before February 2004, but his enterprise really boomed when he went into business with the Garzones and McCafferty in Philadelphia. In the end, the Garzone and McCafferty bodies dismembered over 18 months accounted for a quarter of all the bodies harvested in three and a half years by BTS.

Lee Cruceta was Mastromarino's right-hand man at BTS. He had been a nurse before joining Mastromarino's more lucrative enterprise fulltime in 2003. Mastromarino placed him in charge of the laboratory where tissue and blood samples were stored and distributed. As head of his field operation, Cruceta also led the teams of cutters and supervised the taking of tissue. He and Mastromarino did the bulk of the fraudulent paperwork. Cruceta shared generously in BTS's illegal profits, and even formed his own company to hold his cut.

There were other lower-level employees of BTS who were involved in the stealing of tissue as well. Two of them, Kevin Vickers and Richard Bifone, were granted immunity and testified before the Grand Jury. Another regular "cutter" at the Garzones' funeral homes was Chris Aldorasi. Two women, Darlene Deats and Kirssy Knapp, worked as cutters only infrequently in Philadelphia. Vickers, Deats, and Knapp operated mostly in Rochester, New York, and have been indicted there, along with several funeral directors, for their participation in this multi-state body harvesting ring. Mastromarino,

Cruceta, Aldorasi, and several New York City funeral directors have been charged in Brooklyn.

BTS was not accredited by the American Association of Tissue Banks (AATB), a nongovernmental professional group that accredits tissue banks and publishes standards for safe processing and handling of tissue. But Mastromarino and Cruceta were individually certified by the AATB and, therefore, were familiar with its standards and protocols for safe tissue harvesting, many of which are also required under federal law.

Stealing Body Parts

For a year and a half – from February 2004 through September 2005 – the Garzones and McCafferty permitted teams of Mastromarino’s cutters, usually led by Cruceta, to steal bones, skin, tendons, spines, and sometimes hearts from bodies that the funeral directors were supposed to care for, cremate, and prepare for burial. They did so without the permission or knowledge of those who entrusted and contracted with them to handle deceased family members’ bodies in a particular way. They did it for \$1,000 a body. And they did not care what the cutters took or in what shape they left the body. According to Mastromarino’s BTS documents, the Garzones and McCafferty let Mastromarino’s teams desecrate 244 bodies in this way. In the three states where it operated – New York, New Jersey, and Pennsylvania – BTS records show 1,077 bodies harvested since 2002.

McCafferty was the first to meet Mastromarino. The funeral director told a detective with the Philadelphia D.A.’s office that Mastromarino approached him in February 2004, at the suggestion of Gene Supplee, an employee in the Philadelphia

Medical Examiner's office. Mastromarino asked if McCafferty would be interested in harvesting body parts at his funeral home. McCafferty claimed in his statement that he turned Mastromarino down, but admitted that he referred Mastromarino to his crematory partners, the Garzone brothers. However, BTS checks made out to McCafferty, each in the amount of \$1,000 and signed by Mastromarino, contradict his assertion that he turned Mastromarino down. Moreover, Richard Bifone, who worked with Mastromarino's cutters, testified that he saw McCafferty bring bodies to Louis Garzone's funeral home on a few occasions for harvesting. McCafferty did ultimately acknowledge to the investigator that he received \$5,000 to \$6,000 from Mastromarino in connection with his taking tissue from bodies.

The Mastromarino team's first harvesting of a corpse in Philadelphia is, in fact, documented as having been performed at James A. McCafferty Funeral Home. Records that the FDA requires tissue-recoverers to keep, and to forward along with any tissue when it is sold, list "McCafferty Funeral Home" as the "recovery location." The name provided on Mastromarino's forms for the deceased is "Raymond Brieman" and the time of the recovery is recorded as 1:55 PM, February 19, 2004. Investigation of death certificates for the state of Pennsylvania reveal that "Raymond Brieman" is not the real identity of the body (since no death certificate for anyone by that name could be found). But Mastromarino gave the body an identifying number: BM04-B114. This allowed investigators to trace the tissue cut from the body at McCafferty's funeral home to its sale by BTS to two different tissue processors for \$7,300.

About a week later, the harvesting operation moved to Louis Garzone's funeral home on Somerset Street, across the street from the crematory. A Liberty Crematory

employee, Anthony Garafolo, testified to the Grand Jury about how he, unwittingly, became involved with the harvesting operation in the spring of 2004. McCafferty had hired him to work at Liberty beginning in January 2002. His job, initially, was to pick up bodies at hospitals, nursing homes, the medical examiner's office, and other funeral homes, and to bring them to Liberty for cremation. In the spring of 2004, however, his instructions changed. Garafolo told the Grand Jury how Gerald Garzone accompanied him to pick up a body in Northeast Philadelphia. Instead of taking it to the crematory, as he usually did, Gerald had him leave the body in an alley alongside Louis Garzone's funeral home. When he returned to the funeral home the next day to take the body to the crematory, he noticed that its face was disfigured. He said that it looked as if pieces of flesh had been removed.

Garafolo estimated that he was subsequently instructed to deliver roughly 200 bodies to Louis Garzone's alley – even those whose death certificates listed cancer as the cause of death or gave no cause at all. Even bodies with rigor mortis that were not suitable for harvesting went in the alley. When he returned to take the bodies to the crematory, he found them disfigured, often missing limbs. Some were just torsos. The body bags that held them were full of blood.

At the same time that he was being told to deliver bodies to the alley, Garafolo began to see vehicles with out-of-state license plates parked outside the funeral home. There was sometimes a white Suburban, sometimes a blue Chevy Tahoe, and sometimes a dark blue sedan. He observed men getting out of the cars and taking white coolers into the alley. He would see them enter the home and then leave later with the coolers. And while they were inside Louis Garzone's embalming room, he could hear sawing sounds.

Garafolo testified that he asked one of the Garzones what was going on. His boss told him that the men he saw were medical examiner trainees from New York. Garafolo did not believe him and he asked if the Garzones had permission from families to cut up the bodies. He was told they did. Garafolo said that he finally quit because he was scared of contracting a disease, and because he believed that what his bosses at Liberty were doing was illegal.

The cutters at work

While Garafolo could only surmise what was going on inside Louis Garzone's embalming room, the Grand Jurors heard from two BTS employees who knew. Kevin Vickers and Richard Bifone, who were granted immunity for their testimony, both described a gruesome picture. Bifone participated in almost every theft from bodies in Philadelphia. Vickers, who was being trained to run a similar operation for Mastromarino in Rochester, New York, worked in Philadelphia for only a few months. Both knew that what they were doing was not right.

Vickers had been trained by and worked previously for a legitimate agency, the Rochester Eye and Human Parts Bank. He described its high standards for sanitary recoveries of body parts, 98 percent of which were performed in hospital operating rooms. The process for obtaining consent and medical history from family members, he said, usually took three hours, and involved probing, personal questions. The recovery itself took four hours. Vickers was taught to be meticulous about contamination, changing blades and cleaning incisions so that germs on the outer surface did not infect the interior tissue. He would change protective clothing if he moved to another side of the

operating room and change gloves when he moved to another part of a body. Parts were removed carefully so as not to harm their structural integrity.

In 2003, Vickers injured his hand and went on disability from the Rochester job. When he was ready to go back to work, someone at Regeneration Technologies, Inc. referred him to “Dr. Mike,” describing Mastromarino as someone who was providing RTI with a “phenomenal amount of stuff” and calling him “one of the leading procurers in the country.” Mastromarino saw in Vickers someone capable of opening up a new territory – Rochester – for his illegal enterprise. He offered Vickers \$350 for each body he harvested, a significant increase from the \$25 an hour Vickers had earned at the Eye and Human Parts Bank.

Vickers testified that he worked at Louis Garzone’s funeral home about 12 times, while he was “training.” He encountered Louis and Gerald there, he estimated, four to five times each. The first time he went to the funeral home, he rode down in a white Suburban driven by Chris Aldorasi, one of Mastromarino’s cutters. As was their routine, they did not go to the front door, but entered the funeral home through the side alley. The alley was hidden from Somerset Street by a gate, but as soon as they opened the gate, Vickers saw a body, out in the open, lying on a gurney in the alley. It was covered by a piece of blue Astroturf-like material. A sparrow was perched on the head. From the alley, the cutters entered a small room normally used by grieving families to receive guests. There they changed into hospital-like scrubs. In these supposedly sterile clothes, the team members then went back outside into the dirty alley and entered through another door into a tiny embalming room.

When asked to describe the condition of the room, Vickers answered: “I wouldn’t let my dog stay there.” The floor, he said, was covered with dried blood and pieces of tissue. “It looked like the back of a butcher shop, quite frankly.” There was no refrigeration, no window, and no ventilation. “It smelled like the opposite of disinfection,” he declared. “It was clearly a room plagued with bacteria.” Bifone’s testimony confirmed Vickers’s description of the room.

Vickers testified that the bodies he was asked to cut up were “unfresh.” He knew that they often sat out in the open, with no refrigeration for more than 12 hours, because the cutters sometimes would not go to Philadelphia until the day after receiving a call that a body was ready for harvesting. In his experience, Mastromarino and Cruceta never rejected a body as too old or too diseased. Sometimes the bodies had been sitting so long that no blood could be taken (even though this was essential to allow testing for diseases). Vickers never saw anyone get consent from family members or question the medical history of the deceased.

The procedures routinely used by Mastromarino, Cruceta, and the other cutters were as awful as the condition of the facilities and the bodies. Mastromarino stopped Vickers as he started to scrub his hands and said there was no “need to do that.” Instead of taking four hours to surgically remove tissue, Mastromarino, Cruceta, and their teams ripped bodies apart in 30 minutes, taking anything that could possibly be sold. Rather than removing bones individually, they just “slashed” arms off. Vickers called the others “butchers” and said “they raced to see how fast they could go.” He described the proper procedure for taking just a thin layer of skin from a body, a procedure that takes 35 to 40 minutes. In contrast, he said, Aldorasi hacked the whole skin off in a minute or less.

When the cutters were done mutilating the bodies, they stuffed them in body bags and put them out in the alley to be taken to the crematory.

The criminal procedure

Richard Bifone described the group's routine much the same as Vickers did. In addition, he provided insight into how records were kept of the tissue recovery. Mastromarino hired Bifone, a friend of Chris Aldorasi's, in late March 2004, just after BTS had begun its partnership with the Garzones and McCafferty. Cruceta and Aldorasi trained Bifone to handle the "back table" position, which meant that Bifone set out the instruments and wrapped and labeled the bones and other body parts that the cutters removed. Bifone's training took place at a funeral home in New York, where Mastromarino had been operating for almost two years. On his second assignment, Bifone assisted in harvesting the bones from 95-year-old Alistair Cooke, the famous British-American broadcaster who for years hosted the Public Television series Masterpiece Theater.

Bifone explained to the Grand Jury that a job would be initiated with a phone call from one of the funeral directors, usually Gerald or Louis Garzone, to Mastromarino or Cruceta. The extent of the conversation was basically: "We've got a case." Cruceta would then call Bifone and set up a time to meet along the Pennsylvania Turnpike on the way to Philadelphia. Most often these calls came at night with a meeting time the next morning. The team in most of the Philadelphia cases consisted of Cruceta as team leader and a cutter, Aldorasi as the other cutter, and Bifone as "back table." On a few occasions, there were other cutters, including Vickers; his colleague Darlene Deats; and a woman

identified by witnesses as Mastromarino's girlfriend, Kirssy Knapp. Very occasionally, Mastromarino would accompany them and act as team leader.

When a call came in, Mastromarino would assign each case what he called a "BM number," referring to his company's name, Biomedical. The first recorded Philadelphia BM number was for Raymond Brieman. His number was BM04-B114. The 04 stood for 2004; the B, the second letter in the alphabet, stood for February, the second month of the year. The number following the letter was always three digits, with 101 representing the first body of the month. Thus, the pseudo-named Raymond Brieman was the 14th body harvested during the month of February. The bodies often were not identified by name when the cutters were working on them, but they always had a BM number.

Bifone testified that one of the Garzones usually met them when they arrived at the funeral home. There was typically no discussion about the bodies, except when Louis might tell them to leave a particular body alone. Gerald Garzone would, however, ask if they had a check for him – for the bodies. In response, Cruceta would hand him an envelope.

According to Bifone, none of Mastromarino's people ever met with any family members to obtain consent or medical information about the deceased. Although tissue procurement protocols require that procurers have a consent form that specifies which tissues may be taken, these cutters had no such paperwork. Nor did they check the identity of the bodies they were picking apart. The Garzones never even told them the names of the deceased. The only record the cutters had or kept was a white index card that Cruceta partially filled out as they worked. The cards were pre-printed and had

blanks for name, age, gender, height, weight, time of death, time of blood draw, time of recovery, and a check-off list of tissues.

Bifone testified that Cruceta did not fill out all the information on the card. He would not, for instance, fill in the time of death, and only sometimes recorded the person's name based on information from a toe tag. Bifone said that often the toe tag was illegible, or there might not be a toe tag, in which case, no name was put on the card. Bifone testified that Cruceta did seem to look at the clock and put the starting time of the recovery on the card. He also usually estimated the height and weight of the deceased. Bifone never saw Cruceta or Mastromarino ask for a death certificate or a cause of death.

Sometimes when the cutters arrived there were several bodies waiting for them. These might all be crowded in the cramped room in the funeral home, or some might be on gurneys in the alley. Bifone testified that the first thing they did was draw blood, which supposedly would be used to screen for diseases. In Bifone's early months with the operation, he and the others typically took bones – all the leg and arm bones, and the pelvic bones. At some point, though, they started cutting out much more – ribs, the pericardium, the spine, fascia (a skin-like tissue), and skin from all over the body. He said they always took achilles tendons, though this is not always reflected in the recovery record. A few times, according to Bifone, Mastromarino attempted to take hearts, presumably for the valves.

Bifone testified that on a couple of occasions, while the team was working at Louis Garzone's, James McCafferty brought bodies in his funeral home vehicle for Mastromarino's people to cut up. McCafferty, in his statement, admitted that he was

sometimes present, and said that he saw Louis and Gerald Garzone in the room with the cutters when bodies were being dismembered.

Splitting the spoils

Bifone told the Grand Jury that there was a time when he and the others stopped going to the Garzones' for several weeks. He was told that it was because there was a dispute about money between the Garzones and McCafferty – that McCafferty was demanding that he get paid more for his part in the body harvesting business.

Eventually, in mid-2005, the operation was moved from Louis Garzone Funeral Home to Gerald Garzone's funeral home on L Street. The facilities there were even more cramped, and still filthy. The embalming room was entered from the garage, where bodies were stored without refrigeration. Bifone did not know the reason for the move or whether it was related to the feud with McCafferty. He said that right before they moved, though, one of the Louis Garzone Funeral Home's embalmers had unexpectedly walked into the room while they were harvesting a body. This, according to Bifone, greatly upset Cruceta and Aldorasi. They even discussed "knocking out" anyone who entered in the future.

The Grand Jury reviewed some of BTS's bank records. These revealed \$245,995 in checks written to Garzone Funeral Home, Gerry Garzone, McCafferty Funeral Home, and Jim McCafferty. The checks were endorsed and deposited by Louis Garzone, Gerald Garzone, "Garzone F.H.," and Jim McCafferty. They were all, with the exception of one check for \$995, in even multiples of \$1,000. In the early months of 2004, the checks were

mostly for \$1,000 to \$3,000 – never more than \$8,000. By the summer of 2005, the amounts had grown to \$10,000, \$11,000, even \$12,000.

Bank records also reveal that in 2004 and the first three quarters of 2005, Mastromarino wrote BTS checks to, among others: Cruceta’s “company,” LMC Tissue Recovery Services, totaling at least \$389,605; Chris Aldorasi’s two companies, Chris Aldorasi Funeral Services and MCM Tissue Services, for \$315,134; Kirssy Knapp, or her company – VKM Tissue Recovery Services – for \$123,972; Kevin Vickers for \$5,175; and Mastromarino’s own predecessor company, BioTissue Technologies, for \$86,500.

Without consent

By subpoenaing death records for the city of Philadelphia, the Grand Jury was able to identify 48 of the 244 bodies known to be harvested in Philadelphia by this criminal group over a year and a half. The Grand Jury heard evidence from family members or those responsible for 46 of the 48. These were the people who had made funeral arrangements with the Garzones, McCafferty, or other funeral directors who used Liberty Crematory to perform their cremations. Not a single one of them was asked anything about donating their loved one’s tissue. They certainly never consented, and they were distraught when they learned what had happened. One husband refused to talk to a detective who sought to interview him, insisting that no such thing could have happened to his wife. Although he did not testify, he clearly had not given his consent.

The bodies that the funeral directors chose to hand over to Mastromarino for evisceration were all supposed to be cremated. This was not a coincidence. For one thing, cremations made it easier to deceive the next of kin. Family members testified that they

made explicit contractual arrangements with the Garzones and McCafferty about how they wanted their relatives' remains handled. Some families wanted a memorial service with the urn of ashes displayed. Others wanted to have the ashes returned promptly so they could be buried at a private ceremony, or scattered at sea, or at a summer house. In one case, a friend was trying to honor a Hatboro man's request that his ashes be returned to Germany, his childhood home.

With cremation, these families could not know what the funeral directors had allowed Mastromarino's cutters to steal, or that there was very little left of the body to return. The families could not know how badly the funeral directors had abused the bodies they were to suppose to prepare with dignity. They could not even know if the urns they received contained any part of their family members' remains. That the ashes returned to clients were their relatives' is made more doubtful by the fact that the Garzones falsified records reporting when particular bodies were cremated. In many of the Philadelphia cases where the body was positively identified, the cremation time listed by the Garzones on the official death certificate is at least a day before Mastromarino's men arrived to steal its tissue. In one case, a funeral home's records show that a *burial service* took place the day before the harvesting – meaning that the ashes returned by the Garzones, and buried by the family, could not be those of the deceased.

Another apparent reason for the funeral directors' choice to use bodies bound for cremation is that cremated bodies were more valuable to their criminal enterprise. An October 16, 2006, article in *New York Magazine* quoted Cruceta as saying that the cutters were "careful" – taking mainly leg bones and sewing the body back together – when there was to be a viewing. By contrast, the article said the cutters went "whole hog" when

the body was to be cremated. Cruceta reportedly used a power tool to remove spines in those cases. He told the magazine reporter that in Philadelphia the Garzones wanted the mutilated remains just left on a stretcher so they could be wheeled to the crematory. He said that the bodies were so messy when they were finished that they would pack something around them “just so rolling the body out, they wouldn’t leave a trail of blood and body parts across the street.”

Because BTS used people’s real names for only 48 of the Philadelphia bodies, only those relatives could confirm for the Grand Jury that they did not consent to having parts stripped from the bodies they entrusted to the funeral directors. It is clear to the Grand Jurors, though, that none of the relatives of the 196 fraudulently named bodies consented to this treatment either, especially in light of the fact that BTS forged and falsified documentation in the same manner for those bodies. The jurors concluded that the pattern established in the 48 cases held true for all 244 bodies – no relatives were ever asked for permission to this mutilation of their family members’ bodies.

Endangering the Public

Butchering and stealing pieces of someone’s body after they die, especially when the theft is perpetrated by those entrusted to care for the remains, is sickening enough. But the callousness and criminality of these conspirators did not end there. Knowing that the lives of those who would receive the body parts depended on the condition of the donors and the careful handling of the tissue, the funeral directors and the tissue recoverers flouted all the laws and regulations designed to protect the public.

The Garzones both admitted in statements to an investigator with the Pennsylvania Department of State that their understanding had been very clear: tissue should not be used from bodies with certain diseases (examples Louis listed were AIDS, HIV, hepatitis, leukemia, and cancer) or beyond 75 years old. Yet the death certificates of 16 of the 48 people whose certificates could be found (because Mastromarino used their real names) clearly revealed that they had died of cancer. Five more died of sepsis, meaning their bodies were riddled with infection. One death certificate noted that the deceased had both HIV and hepatitis. And 17 were older than 75 when they died. The conspirators compounded the danger of infection by harvesting unrefrigerated bodies long after death and in a bacteria-plagued embalming room filled with dried blood and tissue.

The Garzones said that when they would call Mastromarino to tell him they had a body ready, they told him the age and the cause of death listed on the death certificate. Still, these bodies – no matter how diseased or decrepit – were harvested and their parts offered for distribution and implantation into unsuspecting patients. The Garzones said that they never gave the official death certificates to the cutters or provided the names of the deceased. They must have known that Mastromarino did not plan on using them.

Fraudulent paperwork

Mastromarino and Cruceta took care of falsifying the records relating to these bodies, so that their parts could be sold at huge profits. (Mastromarino allegedly assured the Garzones, falsely, that the funeral directors' names would not appear on the BTS documents.) Paperwork intended to document donor consent, the health history of the

deceased, the condition of the body, and the time and circumstances of the recovery accompanies every piece of tissue, through each step of processing, until it reaches the ultimate recipient. If it is filled out diligently – and honestly – the paperwork goes a long way toward assuring the safety of the tissue. If it is falsified to deliberately distribute bad tissue for profit, it can gravely endanger those who rely on it.

Mastromarino falsified just about everything in this paperwork, starting with the donor consent form. First he made up the “consenting legal next of kin” – creating spouses and siblings that, according to real relatives’ testimony, do not exist. Next, he procured two signatures to represent phony “witnesses” to the fictitious relative’s fabricated “telephone consent.” Sometimes he signed his own name as one of the witnesses. How he obtained the other witness signatures varied. On a few forms, he signed Gerald Garzone’s signature. On some others, he signed, without permission, the name of his employee Richard Bifone. After a while, for efficiency, he asked Bifone to just sign as a “witness” on stacks of blank consent forms. Lee Cruceta and Chris Aldorasi also signed as witnesses on most of the consent forms – although they, obviously, could not have witnessed an act by a nonexistent person.

In any case, even if consent had been based on a real conversation with a real person, Pennsylvania law – wisely – does not accept telephone consent for anatomical gifts unless the phone call is recorded. (The relevant provision is 20 Pa.C.S. §8613(f): “DOCUMENTATION OF GIFTS BY OTHERS. – Any gift by a person designated in section 8611(b) shall be made by a document signed by him or made by his telegraphic, recorded telephonic or other recorded message.”)

Although they never asked the next of kin to sign them, the funeral directors knew about – and had blank copies of – the consent forms that Mastromarino fraudulently filled out and sent with the tissue as it was distributed for transplantation. McCafferty admitted, in a statement to a detective with the Philadelphia District Attorney’s office, that Mastromarino gave him one, and Gerald Garzone still had his in a file seized by the D.A.’s detectives pursuant to a search warrant.

The next document that BTS was required to submit along with the tissue was an interview with a close family member who could give a detailed medical and social history. The purpose of this is to ascertain if the decedent’s lifestyle put him or her at risk of contracting certain diseases. The form asks about not only illnesses and surgeries, but also tattoos, body piercings, sexual activity, incarceration, and travel. Legitimate tissue banks take the answers to these questions seriously, and they can easily disqualify a donor. Incarceration within 12 months of death, for example, is an automatic disqualifier according to Regeneration Technologies Inc. documents.

Thus, if Mastromarino had honestly answered that question for James Herlihy (a former Philadelphia Naval Yard worker who had been incarcerated for six months until he was transferred to a hospital just before he died), Herlihy’s tissue would certainly not have been distributed to three tissue banks – RTI, LifeCell, and Tutogen. It was just luck that Mastromarino’s crimes were uncovered before Herlihy’s tissue was implanted. His tissue and blood (or, rather, what was submitted as his blood) had passed screening tests, even though Herlihy had hepatitis C and died of cancer.

Mastromarino instead made a game of these forms. Again, his interviewee was the same made-up relative who purportedly gave consent. To add authenticity, he put in

special touches – “Lois Glory” (not a real name) traveled to Mexico in 1981, and “Ernest Meisler” (again, not real) had gone to Canada in the 1980s and 1990s for business.

Norman Card, a Frankford resident who was real, had not had a “hernia repair” or “spinal fusion,” as Mastromarino reported. Had he spoken to real relatives, Mastromarino would have learned that a number of people whose death certificates did not list cancer as the cause of death, or hepatitis C, nonetheless had one or both of these diseases.

Although he added the personal touches – the made-up surgeries, business trips, and causes of death – Mastromarino had others put x’s in boxes answering “no” to several pages of questions that appeared on the forms, asking whether the decedent had certain diseases or conditions. Bifone told the Grand Jury that Mastromarino had him fill in these answers on blank charts based on no information.

Mastromarino also filled out forms purporting to be doctors’ reports on the dead from whom his teams stole parts. For most of 2004, Mastromarino signed these “Patient History” forms, “Dr. M. Mastromarino,” as if the deceased had been his “patient.” On the reports, he invariably certified: “to the best of my knowledge . . . this patient” had no history of HIV, hepatitis, cancer, or certain other diseases or infections. In late 2004, the form was changed and renamed as a “Certifying Physician Interview Form.”

Mastromarino continued to fill these out exactly as he always had, and to sign them – now claiming that a named physician had provided the information in an interview. A detective with the Philadelphia D.A.’s office, who tried to locate these “physicians” at the telephone numbers provided by Mastromarino on the documents, did not find a single phone number or doctor’s name that was legitimate.

Concealing disease and decay

Cruceta and Mastromarino, according to witnesses, took it upon themselves to fill out the important “Recovery Report.” This form is supposed to document the time of death, the cause of death, the time of tissue recovery, who participated in the recovery, what tissues were removed and by whom, and any comments. Mastromarino or Cruceta almost always signed the form for the Philadelphia cases. They invariably report that there were no complications in the procedure. And the recovery time is invariably within 24 hours of the listed time of death – as required by the tissue banks that bought from BTS. (Actually, the 24-hour limit applies only in cases where the body is refrigerated within 12 hours of death – which none of these bodies were. Otherwise the limit is 15 hours.)

The documents on their face seem in order – except that the time of death recorded on the form is never the actual time of death. In fact, the recorded time is often *two days after* the date that appears on the official death certificate. This means that tissue often was not harvested until almost three days after death – a very dangerous situation.

Eighty-one-year-old Joseph Gibson of Philadelphia, for example, died at the University of Pennsylvania Hospital at 9:55 PM on May 27, 2005, of stomach cancer. Yet the “Recovery Report” submitted by BTS stated that he had died at 10:00 PM on May 30. His tissue recovery was not completed until 6:45 PM on May 31 – 92 hours after he died. BTS received more than \$2,518 for Gibson’s tissue, which has been implanted in at least seven patients. McCafferty Funeral Home told Gibson’s widow that there was a delay at the crematory because it was Memorial Day weekend. At the precise time that

Cruceta and Aldorasi were stripping Gibson's tissue from his body, family and friends were gathering at a home in Bensalem to remember him.

Another body – that of a Philadelphia woman, Diane Thomas, who died of metastasized cervical cancer – sat out for 113 hours before Cruceta and his team dissected her remains. Even though this tissue must have been crawling with bacteria, RTI paid BTS \$3,450 for it, and another company, Lost Mountain Tissue Bank, paid \$5,520. Thomas's tissue was implanted into at least 15 people. The body of Aileen Scully of Philadelphia sat out nearly 100 hours before it was harvested. BTS sold her tissue for \$5,386.

Mastromarino also falsified birth dates and social security numbers. If he decided to admit – just for variety – that a recovery did not take place within 15 hours of his own fabricated time of death, he then claimed that the body was refrigerated, an impossibility at the Garzones' facilities. He always asserted that the deceased did not die in a hospital, although that was rarely true. He had to claim this in order to explain another lie he recorded for each of the bodies – that there were no medical records. Moreover, because his recoveries often happened so long after the actual time of death, he usually claimed that the deceased was “last seen” with “no evidence of trauma” after the person had in fact died. Joseph Gibson, for instance, was reportedly seen at 10:00 PM on May 30, according to Mastromarino's record-keeping. That was three days after Gibson had died.

The final document that Mastromarino sent along with the tissue harvested at the Garzones' funeral homes was a fabricated death certificate. These falsified forms should have raised alarms with the tissue banks with which he conducted business. The forms were barely filled out – including nothing but a name, an incorrect age, the wrong time of

death, an illegible certifying signature, no stamp or seal, and almost always some sort of heart attack listed as the cause of death.

All these inaccuracies were not the result of sloppiness or lack of care. They were motivated by criminal greed and calculated to return maximum profit. Forgoing actual consent maximized the supply of tissue with a minimum of effort. Lying about the health of the deceased and the cause of death minimized rejections. And falsifying the age of the deceased increased the conspirators' take. For example, one of the positively identified bodies was that of 89-year-old Joshua Carter, a former Campbell Soup Company assembly-line worker who had died at Philadelphia's Mercy Hospital on March 1, 2004, at 12:15 AM. When Mastromarino submitted his blood to RTI for screening, he not only lied about Carter's time of death (to hide the fact that his tissue was not removed until more than 48 hours after he had died), but he also subtracted 29 years from Carter's actual age, claiming to RTI that he was only 60 years old. By understating Carter's age, Mastromarino was able to exact a higher price from RTI. According to a "Reimbursement Schedule" in the contract with BTS, RTI agreed to pay \$8,750 for musculoskeletal tissue from a body under 65 years old, but only \$4,320 if the donor was older.

Bad blood

As dangerous as it was to fake these documents, at least as bad was the fraud that Mastromarino and Cruceta perpetrated with blood samples supposedly drawn from the bodies they harvested. The evidence makes it clear that Mastromarino and Cruceta

deliberately and routinely sent blood for testing that did not come from the tissue “donors.”

Central to any regulatory effort to assure tissue safety is the screening of blood in order to test for various infectious diseases – at a minimum, HIV, hepatitis B and C, and syphilis, as well as HTLV I and II (viruses common among drug users that can cause leukemia and lymphoma). To comply with FDA regulations, any tissue banks that purchased tissue from Mastromarino’s company, Biomedical Tissue Services, would require a serology report showing that the blood of the “donor” tested negative for these diseases.

Regeneration Technologies, Inc. (the company that was also one of Mastromarino’s principal customers for tissue) did all of the blood testing for BTS. The procedure called for BTS to send blood samples to RTI immediately after the recovery of tissue. Each blood sample was labeled with a BM number and was to correspond to tissue with the same BM number, taken from the same body. BTS retained the tissue until the serology report was completed. If the results came back negative (that is, no disease found), then BTS would distribute the tissue with that same BM number to RTI and other tissue banks. These included: Tutogen Medical, Inc., a tissue bank near RTI in Alachua, Florida; Lost Mountain Tissue Bank in Kennesaw, Georgia; Blood and Tissue Center of Central Texas, in Austin; and LifeCell Corporation in Branchburg, New Jersey, which took mainly skin.

On the first five bodies harvested at Louis Garzone’s funeral home, this testing seemed to be effective. Blood samples submitted from all five tested positive for diseases that rendered their tissue unsuitable for use – three of the corpses were infected with

hepatitis C, one with hepatitis B, and one with syphilis. Because the blood samples for these bodies tested positive for contagious and life-threatening diseases, RTI did not purchase the tissue. Still, its agreement with BTS required RTI to pay Mastromarino \$1,000 per rejected body – an arrangement ill designed to encourage careful screening of potential donors.

After these initial rejections, however, the rejection rate dropped dramatically. An analysis of the blood samples explains why. A comparison of the serology reports for all of the blood submitted to RTI from Philadelphia bodies shows that the same blood was often submitted for more than one body. Also, DNA testing performed on the blood of three bodies harvested at Louis Garzone’s funeral home in April and May 2004 conclusively proves that the blood submitted by Mastromarino and Cruceta was not always from the same body as the tissue. It also confirms that BTS did, in fact, submit the same blood for more than one body.

The Grand Jury subpoenaed and reviewed the serology reports for all of the bodies harvested in Philadelphia. Focusing first on the reports for blood that tested positive for diseases, several unusual patterns were evident. In at least three instances, blood samples from bodies harvested within days of each other were found to be the same blood type and they tested positive for exactly the same antibodies. For example, blood samples submitted for “Joan Rogers” (BM04-K108) and “Ralph Mattai” (BM04-K111) both tested positive for HIV and HCV (hepatitis C), and they were both B negative, a blood type that only 2 percent of the population have. The two bodies were harvested just two days apart. Similarly, two bodies (BM04-F142 and BM04-F143) harvested on June 29, 2004, both tested positive for the same hepatitis B antibody, and

were AB negative – another rare blood type. Caroline Hartill, RTI’s vice president for Quality Assurance and Regulatory Affairs, was asked about these results. She testified that in these instances, it was very unlikely that the bloods came from different donors.

Hartill also testified about DNA testing that was performed on some of the samples. She explained that some of the people who have been implanted with BTS tissue have subsequently tested positive for HIV or hepatitis or syphilis. When RTI has been notified of these positive results, it has in some cases ordered DNA testing on retained samples of tissue and blood submitted as having come from the donor whose tissue was implanted in the infected patient. The reason RTI does this is because the blood samples provided with the implanted tissue were all screened and found free of these diseases before the tissue was implanted. Therefore, if it could be proved that the sampled blood and the implanted tissue came from the same donor, that would be strong evidence that the tissue had not caused the infection in the implant recipient.

The DNA from 19 samples of blood and tissue, all from BTS, was tested. Three were from sets of tissues harvested from the Garzones’ funeral homes. The results of these tests were troubling – and telling. Of the 19 blood/tissue pairs sent for testing, 9 did not match. Two of the three Garzone samples did not match. What this means is that tissue in cases where the blood sample did not match was accepted and distributed by tissue banks without any valid screening for these diseases.

This is especially dangerous when bodies are being harvested in unsanitary places like Louis Garzone’s funeral home. A review of death certificates for people who were buried or cremated by the Garzones’ funeral homes during the period when Mastromarino and Cruceta were harvesting body parts there reveals that a substantial

percent died of diseases that should automatically have disqualified them as donors – HIV, hepatitis, sepsis, or cancer. Another large group of the deaths were drug-related, also a disqualification. In addition, Louis Garzone’s funeral home is located just a block from a section of Philadelphia known for its high incidence of drug use and prostitution. That bodies harvested here were not properly screened is especially frightening.

Joseph Pace, whose tissue was tainted by HIV, hepatitis, sepsis, and cancer, is a case in point. The Garzones had provided the corpse for harvesting even though the death certificate plainly listed infectious and deadly diseases. Cruceta had let the body sit unrefrigerated for 52 hours before cutting out the tissue. The tissue itself was handled with total disdain for sanitary protections. Even so, had Cruceta not falsified the blood sample, the tissue banks would have rejected Pace’s body parts. Even with all the fraud and forgeries and falsifications that the funeral directors and BTS had undertaken to make the sale, an accurate blood screening could have provided a safeguard to prevent the distribution of the contaminated tissue. The fact that Cruceta and Mastromarino intentionally mislabeled the blood demonstrates that they were not just reckless in their actions, but that they deliberately distributed potentially lethal body parts for use by the medical community.

Besides proving that Mastromarino and Cruceta sent blood samples for testing that were not from the same bodies as the tissues they sent, the DNA testing showed something else. The one Garzone blood sample that did match its associated tissue, also matched the tissue of a body supposedly harvested at New York Mortuary Services in East Harlem more than a month later. The blood sample was drawn from “Robert Cambel” (not his real identity) (BM04-D108) on April 5, 2004, at Louis Garzone’s

funeral home. On April 8, 2004, BTS was notified that Cambel's blood test results were good. His tissue was then distributed to RTI and LifeCell for a total of \$6,450. More than a month later, Cambel's blood again passed the serology tests. This time, however, Cruceta – who BTS employees said was in charge of sending out the blood and tissues – sent Cambel's blood with a different BM number, one corresponding to "Craig Milber" (BM04-E118), purportedly harvested at New York Mortuary on May 19, 2004. Based on Cambel's good blood, RTI and Tutogen bought the tissue from "Milber's" body for a total of \$9,425.

Body parts relabeled

Another troubling feature of this pattern is that "Craig Milber" may not have been harvested at all on May 19, 2004. Richard Bifone provided the Grand Jury with his billing records, which recorded in great detail the date, place, number of bodies, and who the cutters were for the jobs that he worked. These were the records he submitted to bill for his work. For May 19, 2004, Bifone's records reflect that he, Cruceta, and Aldorasi did one body in "(NYC)" (Bifone's shorthand for the New York Mortuary).

Mastromarino, however, sold tissue to RTI and Tutogen from *two* bodies supposedly harvested that day at New York Mortuary. Mastromarino's paperwork lists himself as the team leader, but Bifone's records don't show Mastromarino being there.

Bifone testified about a pattern that he noticed that could explain this discrepancy. He told the Grand Jury that there was a whiteboard in the BTS lab where BM numbers were listed when calls came in from funeral directors. Bifone said that he noticed that numbers were sometimes skipped from the last time he had gone out on a job. Usually he

was told that BTS had sent someone else out on the job, or some explanation like that. But one time Cruceta told Bifone that a missing BM number was for “one of Doc’s research cases, don’t ask.”

Bifone did not ask at the time. But after detectives showed up at his door in October 2005 to question him, Bifone asked Cruceta and Aldorasi if there was anything he needed to know. Cruceta answered, “Remember I told you about Doc’s research cases?” Bifone then related Cruceta’s explanation, that “they were . . . leaving bodies back for a rainy day, not sending them all. When they needed money. You know, keeping certain bodies back, certain bones back and then putting new labels on them at a later date and sending them out to the companies.”

In testimony consistent with what Cruceta related to Bifone, Kevin Vickers – trained by Mastromarino to run the entire operation in Rochester, New York – told the Grand Jury that, according to proper procedure, when a serology report comes back positive for a disease, the tissue from that body should be incinerated. Yet, he said, he had no knowledge that that was ever done by Mastromarino or Cruceta.

Caroline Hartill, the vice president at RTI, said she also had been concerned about what Mastromarino was doing with the tissue associated with rejected blood. She explained that the contract between RTI and BTS entitled Mastromarino to be paid recovery costs even when the tissue was rejected because of a failed serology test. So, when tissue was rejected, Mastromarino billed RTI for \$1,000 per body. RTI became concerned, Hartill said, because it had no record of what he was doing with the rejected tissue. It was her understanding that Mastromarino had advised RTI in the past that he had a “research outlet” for the tissue.

But Hartill decided that if Mastromarino did have another outlet, then that purchaser should pay the recovery costs and not RTI. RTI, therefore, changed its policy: it stopped paying for rejected tissue – unless BTS provided evidence that the tissue was destroyed. What happened then, according to Hartill, is that BTS started providing purported evidence of disposal. (At least it provided receipts showing that a waste management company picked up boxes from BTS – boxes packed by the same people, Cruceta and Mastromarino, who falsified all the other tissue records.) Had Mastromarino really had a “research outlet” that paid him for the diseased tissue, it is curious that he just then started “disposing” of it instead.

Mary Piccirillo, the former office manager for BTS, told a detective with the Philadelphia District Attorney’s office that the FDA also was concerned about what Mastromarino was doing with the rejected tissue. According to Piccirillo, Mastromarino did not give the FDA the story about a “research outlet.” He told the federal regulators that he was incinerating the tissue at New York Mortuary – an answer at odds with Vickers’ testimony.

THE SCOPE OF THE HARM

The victims of this criminal enterprise number in the thousands. First, there are all the husbands and wives, mothers and fathers, sisters and brothers, and children of those whose bodies were cut up without consent. There are all those who entrusted Louis Garzone, Gerald Garzone, and James McCafferty to handle their family members' funerals in 2004 and 2005, who now must wonder if their loved ones were cut up and sold. Customers of other funeral homes, who have never heard of the Garzones or McCafferty, but whose relatives were sent to Liberty for cremation, cannot know that these unscrupulous crematory operators did not steal their bones and skin and leave them in a heap in a bag in an alley. Given the funeral directors' callous treatment of the bodies and the falsified documents that recorded people being cremated before their parts were harvested, many families cannot even be confident that the ashes they have received or buried are those of their loved ones.

Then there are the recipients of all the tissue that was fraudulently processed to evade laws and regulations meant to protect the public. The harm to these victims might be that someone's new bone implant does not hold up because it came from somebody much older than it should have. Or a tendon might not work because its integrity was compromised by the high levels of radiation needed to kill bacteria that infected it. Painful surgeries might be unsuccessful because the tissues used were not as advertised. Or a patient could die because transplanted tissue brought with it HIV, or hepatitis, or a deadly fungus.

Through RTI alone, more than 2,000 people have received tissue stolen from bodies at the Garzones' funeral homes. (LifeCell and Lost Mountain have not yet complied with subpoenas for this information.) The tissue recipients are from all over the United States, Canada, Korea, Italy, and Greece. BTS tissue – again, just that distributed by RTI – has been implanted in more than 200 Pennsylvanians. Civil litigants estimate that more than 19,000 BTS tissues may have been implanted in people around the world. Locally, the *Philadelphia Daily News* has reported that BTS tissue has been implanted in at least 16 patients at eight hospitals in the Philadelphia region.

More than a hundred people across the country have filed lawsuits related to implants from tissue originating with BTS. In Philadelphia, at least one woman contends that she contracted hepatitis C from a bone implant that came from BTS. Meanwhile, three patients implanted with BTS tissue at Shore Memorial Hospital in Somers Point, New Jersey, have tested positive for infections.

Robert Rigney, the chief executive officer of the American Association of Tissue Banks (AATB), testified before the Grand Jury to the importance of complying with all of the screening and handling regulations. He cited a case from Minnesota where a 23-year-old died following elective knee surgery to repair a torn anterior cruciate ligament (ACL). He died because the cartilage implanted during his surgery was not recovered until 19 hours after the death of the donor. In that time, without refrigeration, a deadly fungus grew on the donor's tissue. Because the fungus formed spores, it was able to withstand the sterilization process, and the 23-year-old developed an overwhelming infection that killed him.

Rigney testified that in the Minnesota case two AATB-certified tissue procurement agencies had refused to recover the tissue because the donor had been dead too long. AATB protocols require harvesting within 15 hours of death, or 24 if the body is refrigerated. This tragic case clearly points out the enormous danger posed by BTS's careless practices: almost all of the tissue from the Garzones' funeral homes was harvested well beyond the 15-hour limit – and none of the bodies was refrigerated. Then the conspirators took pains to cover up this fact in the falsified documents that accompanied the tissue they distributed.

After reviewing BTS's practices, the FDA wrote that “deficiencies, including your failure to create and maintain accurate records, are so serious and widespread that FDA finds there are reasonable grounds to believe that they present a danger to public health.”

The economic toll of these crimes is not insignificant either. Patients, hospitals, and others who paid considerable sums for inferior and tainted tissues were all defrauded. Of course, by the time these tissues reached the ultimate recipient, their price tag was much higher. Even so, looking at the amounts that just a few of the distributors paid to BTS is still telling. For tissue stolen from bodies at the Philadelphia funeral homes:

- RTI paid BTS \$628, 270, plus “facility fees” of \$500 per body.
- LifeCell paid BTS \$307,951.
- Blood and Tissue Center of Central Texas paid BTS \$38,000.
- Tutogen paid BTS \$97,875.
- Tissue Management Services, a company in Scottsdale, Arizona, paid BTS at least \$33,665 for tissue that went to Lost Mountain Tissue Bank.

The total amount that these companies paid to BTS for tissue stolen in the Philadelphia homes was at least \$1,105,761. They paid at least \$3,776,180 for tissue harvested by BTS from funeral homes in New York, New Jersey, and Pennsylvania in 2004 and 2005. It was in all probability more than this – considering that BTS was paid more than \$19,000 for the parts taken from just one body harvested in Philadelphia, and the company harvested 1,077 bodies in the three states.

WELFARE FRAUD

Apparently, even the profits from stealing and selling tissue were not enough to satisfy the greed of Louis and Gerald Garzone and James McCafferty. The Garzones claimed to federal investigators that a “leaky pipe” destroyed all their client records for 2004 and 2005. Yet, when detectives from the Philadelphia District Attorney’s office executed a search warrant at the Garzones’ funeral homes, they discovered a few files (some wedged far back in a file drawer behind a divider) that the alleged deluge had somehow spared. It seems the prospect of eking out just a little more in fraudulent gains from these bodies was too much for Louis and Gerald Garzone to resist.

Records found in both Garzone funeral homes included case files for Juliana Thompkins and John Hayes, whose bodies had been harvested on August 29, 2005, and September 9, 2005. The stolen body parts had already been distributed by RTI and Lost Mountain Tissue Bank – despite Hayes’s death from bacterial sepsis and Thompkins’s chemotherapy treatments and kidney infection. But there was still more money to be made off the corpses.

Louis Garzone had filed a request for burial payments with the Pennsylvania Department of Welfare for Thompkins; Gerald Garzone had done the same for Hayes. The paperwork for these claims was in the files discovered by the detectives, including three different bills for goods and services for Hayes. The multiple bills showed that the Garzones had charged more than one party for the funerals. The D.A.’s office alerted the Pennsylvania Inspector General’s office, which launched an investigation – led by regional manager Betsy Ivey – into welfare fraud.

What the investigation revealed was that Gerald and Louis Garzone and McCafferty used their businesses and the bodies brought to them for burial and cremation as tools for more than one criminal scheme. In 2004 and 2005, while reaping \$1,000 for each body they made illegally available to Mastromarino's cutters, the funeral directors also exploited customers who were eligible for state assistance as a means to cheat the Pennsylvania Department of Public Welfare (DPW).

The DPW offers help to its welfare recipients for funeral expenses. If an eligible person dies with no resources to pay for their own funeral, the department will pay \$750 for the burial. The program operates by enrolling funeral directors as providers. These funeral directors sign a "provider agreement" with the DPW in which they agree to provide the burials of welfare recipients in return for reimbursement from the state. According to the terms of the agreements, the funeral directors are not permitted to solicit or charge the recipient or anyone else for these funeral services. The funeral directors are expected to collect any burial funds or insurance that the deceased may have, apply them toward the cost of the funeral, and then reduce the charge to the welfare department accordingly. They are required to notify the department of any funds they receive for the burials. This is not how the Garzones and McCafferty operated.

Investigators for the state Inspector General's office found 112 cases in 2004 and 2005 in which the Garzone brothers and McCafferty defrauded the DPW, collecting payment for burial services from families, insurance policies, nursing homes, even charity, and then charging the welfare department, falsely claiming that they had been paid nothing for the funerals. (In three of these cases, they did not receive payments from the family, but still made fraudulent requests that the family was unaware of.) On 49 of

these claims, they forged signatures of family members or others responsible for the deceased. In at least four of these cases, they double-charged families and the state for bodies for which they had also received \$1,000 from Mastromarino. (If the true identity of more of the harvested bodies were known, this number would undoubtedly be much higher.) In total, the funeral directors received \$183,611 from families and other sources on these cases. They defrauded the state welfare department for an additional \$84,000.

The Garzones, who accounted for the vast majority of the welfare fraud cases, displayed their callousness in this criminal scheme as well. John Jarrell, a welfare fraud supervisor for the state Inspector General, testified about numerous interviews he conducted with family members who had made funeral arrangements with the Garzones. He said that he needed to take a box of tissues with him, because so many of the bereaved cried through their heart-wrenching stories. One young Kensington woman, Christina Gargel, told him that she had gone to Gerald Garzone's funeral home to arrange for the burial of her stillborn baby, Hailey Gargel. Although Gerald Garzone had a duty as an eligible welfare provider to inform Gargel that the state would pay \$750 toward the baby's burial, he did not do so. Instead he charged the grieving mother \$850 for the funeral.

Gerald Garzone then failed to provide what he had agreed to. Gargel had asked for an open casket at the church, but when she arrived, the casket was closed. He refused her request to open the casket so that she could see her baby one last time. When she asked why, he responded, "because I say so." He subsequently filed a request for burial payments with the DPW. On the form Gerald Garzone forged Christina Gargel's

signature and falsely claimed that she had paid him nothing for Hailey's funeral. As a result of this fraudulent submission, the state paid him \$750.

Jarrell found that the Garzones and McCafferty never informed the people he interviewed that welfare would provide burial payments. In fact, one Fishtown woman, Linda Hall, told him that she had specifically asked Louis Garzone if welfare would pay for her mother's cremation. He told her it would not. He charged her \$750 and, because she could not pay it in a lump sum, he came to her house every month, for seven months, to collect \$100 cash payments. Meanwhile, Louis Garzone forged her signature on the DPW form to request burial payment from the welfare department. He falsely claimed that he received no payment from Hall.

Jarrell was asked by the Grand Jurors about one case in which Gerald Garzone charged one family \$8,000 and still filed a fraudulent welfare claim. Jarrell responded that his interviews revealed that all three funeral directors took everything that people had, irrespective of the services provided, and despite the fact that their contract with the state prohibited charging these people anything. The funeral directors cleaned out people's savings, they took the full amount of any insurance policy, they emptied nursing home accounts, and sometimes charged nursing homes – even if they were providing nothing but a cremation.

Louis Garzone even cheated the welfare department, and others, in a highly publicized case of five children who were killed in a Tacony house fire in June 2005. The tragedy was prominent in the news, not only because of the horror of the events, but also because Stevie Wonder, the entertainer, offered to pay for the funerals for the children. Three of those killed were children of Shannon Bowers, a welfare recipient. Bowers

herself was injured in the fire and was in Temple University Hospital when arrangements were made for the children's funeral. According to Jarrell's interviews, Louis Garzone had initially approached Shannon Bowers's mother and offered to bury the children for free. When Stevie Wonder subsequently made his generous offer, Bowers's mother went to talk to Louis Garzone. She asked if he was still willing to bury the children for free. In response he reportedly said, "I'll tell you what, why don't we take the Stevie Wonder check and we'll put it in a bank account, so when [Shannon Bowers] gets out of the hospital, we'll give her the funds and it will give her the opportunity to start over."

When Bowers got out of the hospital, however, and went with her mother to ask Louis Garzone for the money, he told them that his brother (presumably Gerald) had cashed the check and spent it. The Bowers, not understanding what Louis was telling them, said that was all right, Louis could give them the money out of his account. To which he is said to have responded: "Lady, I don't think you understand, the money has been spent; it isn't here anymore." Despite receiving \$1,959 per child from Stevie Wonder, Louis Garzone filed a welfare claim for \$750 for each child, claiming that he had received no money toward the funerals.

HISTORY OF THE INVESTIGATION

Michael Mastromarino, Lee Cruceta, and the funeral directors conducted their massively fraudulent operation for three and a half years (one and a half years in Philadelphia) under the noses of federal and state regulators and private auditors. They were supposedly audited by the Food and Drug Administration, by private companies certified by the American Association of Tissue Banks, and by New York state's health department (in the cases involving New York funeral homes). The Philadelphia funeral homes were subject to Pennsylvania's Funeral Director Law, which requires licensure and permits inspection of funeral homes. Yet none of these auditors and monitors detected what was going on. It was a New York City police detective, called to investigate a financial matter by the new owner of one of the New York funeral homes, who noticed that something was amiss.

New York and the FDA

In November 2004, Detective Patricia O'Brien was called to investigate whether the former owner of the Daniel George Funeral Home in Brooklyn had stolen money intended for pre-paid funeral arrangements. The first thing that caught her attention when she visited the home was a room, separate from the embalming room – and secreted – that looked more like an operating room. As she delved into the home's old files, she discovered that the previous owner had been running more than a funeral business. O'Brien's suspicions launched an investigation in New York in the fall of 2004.

In July 2005, according to Mastromarino's office manager Mary Piccirillo, an investigator from Brooklyn, accompanied by a Fort Lee, N. J., police officer, served a subpoena on Mastromarino. Mastromarino told Piccirillo that it was something to do with his old dental practice. But two weeks later, she noticed that three boxes of old donor records, from 2002 and 2003, were missing from a closet in the office. Confronted by Piccirillo again, Mastromarino first said that he did not know where the records were. She asked again and he said: "OK, maybe I took them to storage." He told her that there was nothing to worry about. Two weeks later, Piccirillo said, Mastromarino's assistant Chris Aldorasi was picked up for questioning by Brooklyn detectives.

None of this apparently slowed down Mastromarino's operation. In July 2005, BTS teams stole parts from 14 bodies at Gerald Garzone's funeral home, and 33 in New York and New Jersey. In August, they harvested 24 bodies at Garzone's, and 23 elsewhere. They continued to operate through September.

The Food and Drug Administration did not learn about the Brooklyn investigation until late September 2005. A regulatory officer with the FDA found out about the investigation when she called to schedule an inspection of LifeCell, the New Jersey-based company that was one of BTS's tissue customers. She was informed that the company had received a subpoena from the Brooklyn D.A.'s office regarding BTS. She then asked Jacques Maravic, a special agent in the FDA's Office of Criminal Investigations, to find out what the subpoena was about. Maravic testified that he then called the Brooklyn D.A.'s office and confirmed that it was investigating BTS.

The FDA regulatory officer told Maravic that LifeCell had hired a consultant in Colorado to review medical charts of donors. On September 28, the consultant, identified

in news accounts as Dr. Michael Bauer, reportedly attempted to contact a physician listed by Mastromarino as the doctor of one of the “donors.” When he dialed the telephone number provided by Mastromarino on the donor’s records, Bauer reached a pizza parlor. Bauer said he checked a number of other physician phone numbers listed on BTS donor charts, as the Philadelphia detective would later, and all of them were bogus. He reported what he found to LifeCell, which passed the information on to the FDA.

According to Piccirillo’s statement to Detective Gilbert Brook of the Philadelphia D.A.’s office, she arrived at work at BTS on Friday, September 30 at around 6:30 AM. She said that Cruceta arrived at 8 AM, which was unusually early for him. Cruceta told Piccirillo that “something is going on.” He told her that someone from LifeCell had been at the office the night before. The president of Lost Mountain Tissue Bank, David Wade, was with Mastromarino that Friday morning. According to Piccirillo, Mastromarino told them that he was taking Wade to the airport. He said that he had an “appointment with Philadelphia” on Monday, October 3, and that she should come in on Tuesday.

Once notified, the FDA responded promptly and effectively. On Tuesday, October 4, 2005, it began an inspection of BTS, which included visits to the Garzone and McCafferty funeral homes. Three weeks later, the FDA notified the public about its investigation. According to its news release, distributors of BTS tissue were recalling any unused tissue and notifying doctors who had implanted the tissue.

The FDA’s investigation found that BTS documents:

- contained inaccurate donor ages and cause of death;
- failed to disclose that donors had been hospitalized;
- listed fictitious spouses on consent forms;

- misstated the length of time between death and tissue recovery.

The FDA's inspections of Louis and Gerald Garzone's funeral homes confirmed Vickers's opinion that the facilities were unsanitary and unsuitable for tissue recovery.

On October 7, 2005, FDA investigators went to Gerald Garzone's funeral home as part of their probe. They were unable to review the funeral home's records, however. Louis and Gerald Garzone both told the FDA representatives that their records from 2004 and 2005, from both funeral homes, had been destroyed by a leaking pipe in Louis's basement, just a few days before the investigators arrived. They claimed that they threw them out, and that the trash had been collected on October 3 or 4.

Gerald Garzone acknowledged to the FDA inspectors that Mastromarino had contacted him on October 3, and again on October 4, to warn him that the FDA was investigating and that the Garzones should expect a visit. Richard Bifone testified that Cruceta called him when the FDA was inspecting BTS records. According to Bifone, Cruceta instructed him to delete from his computer the records he kept of his BTS jobs.

While executing a search warrant at Louis Garzone Funeral Home in March 2006, Detective Brook found a few 2005 files from pre-October 3. These were wedged behind a divider in a basement file cabinet that Louis Garzone claimed had been sprayed by the leaky pipe. The drawers of the file cabinet were empty except for these few files. Det. Brook testified that there was no evidence of water damage to the file cabinets, or even that they had ever been wet. The files he retrieved from behind the divider were dry and in good condition.

The FDA's findings, outlined in the October 2005 press release, were detailed in a January 31, 2006, letter to Mastromarino ordering him to cease operation. The FDA has

aided this Grand Jury's investigation by sharing the information gathered by its agents that relates to the operations of BTS and the funeral directors in Philadelphia.

Pennsylvania's funeral home probe

That funeral homes in Philadelphia were partners in Mastromarino's criminal enterprise was not made public until February 23, 2006, when the Brooklyn D.A.'s office announced an indictment of Mastromarino and others in New York. The Pennsylvania Department of State, which is responsible for licensing and inspecting funeral homes, began an investigation in March 2006. The department's investigator interviewed McCafferty and both Garzones.

McCafferty denied providing bodies for harvesting, but said that he had referred Mastromarino to his crematory partners, the Garzones. Louis and Gerald both admitted that they had let Mastromarino take body parts from their funeral homes for \$1,000 per body. While he was looking into the tissue harvesting activities, the state investigator noticed that the license for Louis Garzone's funeral home had expired in February 2004 and had never been renewed. In June 2006, the State Board of Funeral Directors entered into an agreement with Louis and Gerald Garzone for them to voluntarily surrender their individual funeral director's licenses and their funeral home licenses. (It is unclear why Louis Garzone Funeral Home even had a license to surrender, if it had expired in February 2004.) Even though they had admitted to the FDA and state investigators that they had allowed the harvesting of bodies in their homes, they reportedly admitted no wrongdoing. This agreement was announced on June 9, 2006.

The Garzones still in business

On the very day that the Secretary of the Commonwealth announced that the Garzones were surrendering their licenses and “that their establishments will be closed,” a letter was sent from Pennsylvania’s Department of State to “Mr. Garzone.” The letter was from the administrator for the State Board of Funeral Directors. It stated that Garzone’s request to register the name “Garzone Funeral Home, Inc.” with the State Board of Funeral Directors, in anticipation of applying for a funeral home license in Pennsylvania, was approved. On July 5, 2006, Articles of Incorporation for “Garzone Funeral Home, Inc.” were filed with the Department of State, even though there already was a “Garzone Funeral Home, Inc.” incorporated in 1975, and owned by Louis Garzone. The incorporator of this second Garzone Funeral Home, Inc. is listed as James V. Garzone, a brother of Gerald and Louis who has not lived in Philadelphia for years. The address of “Garzone Funeral Home, Inc.” is listed as 4149-51 L Street – the same as Gerald’s “Garzone Funeral Home” – the very establishment that the Department of State had supposedly closed down.

On September 22, 2006, Louis Garzone wrote a check from the bank account of Louis Garzone Funeral Home to the lawyer who had handled the licensing for the “new” Garzone Funeral Home, Inc. On the \$1,000 check, Louis Garzone wrote a notation: “Thank You.”

In November 2006, the state Board of Funeral Directors issued a license for Garzone Funeral Home, Inc. It is signed by the Commissioner of the Bureau of Professional and Occupational Affairs. The board also approved a branch office of the

business – at Louis Garzone’s address, 1830 East Somerset Street. Thus, both Louis and Gerald continue to run their businesses, pretty much as they did before.

In order to evade the law and their supposed banishment from the funeral business, Louis and Gerald hired another funeral director, Frank Gatto, ostensibly to act as funeral home “supervisor” at Louis’s facility on Somerset Street. Gatto admitted to the Grand Jury that he has never met James Garzone, the purported owner of the funeral home corporation and his putative boss – although he did claim to have seen a photograph. It was Louis and Gerald Garzone who hired Gatto and who still run the show. Gatto acknowledged that even though Louis and Gerald lost their licenses, they have continued on as if nothing happened. Except that they seem to understand that they need to impersonate Gatto sometimes over the phone when they are making funeral arrangements with clients – something that Gatto has learned of from customers and from Gerald Garzone himself. Gatto said that all phone calls to the funeral homes are forwarded to Gerald and Louis’s cell phones.

Liberty Crematory remains in business and is still owned by James McCafferty and the Garzones. McCafferty’s mother’s funeral home is still in business. McCafferty retains his funeral director’s license.

REGULATION AND OVERSIGHT

Funeral homes and tissue agencies are both ostensibly subject to substantial regulation. Funeral homes must be licensed and are regulated by Pennsylvania law. Tissue procurers and processors are overseen by state and federal regulators, by companies that are their clients, and by a nongovernmental organization, the American Association of Tissue Banks. Yet none of these laws or regulations prevented Biomedical Tissue Services and funeral directors in New York, New Jersey, and Pennsylvania from trafficking in stolen and tainted body parts for three and a half years, endangering thousands of people worldwide. And none of the systems set up for oversight detected or deterred their criminal enterprise. The ease with which these few crooked men could make millions of dollars, evading the regulations covering their businesses, clearly demonstrates that the current laws and regulatory framework are inadequate: they fail to take into account the enormous incentives and opportunities to commit fraud in the body tissue industry.

The tissue business

The tissue trade is booming. Hospitals, universities, pharmaceutical companies, and surgical tool manufacturers all need human tissue for medical treatment, research, and medical instrument production. Recent technologies have created a growing number of therapeutic uses in particular. Tissue harvested from cadavers often is transplanted in whole or in a processed form to a living person. Skin can be used for grafts for a burn victim; bones can be powdered and molded into a glue-like paste to fill in the gaps of a

forearm fracture; ligaments can be extracted from a dead body and inserted in knees. Such advanced procedures provide astonishing medical benefits. But with availability limited by federal and state requirements for consent and disease screening (92 percent of potential donors at Philadelphia area hospitals are rejected because of age or disease), the demand for human tissue far outstrips the supply. The opportunity to profit is great.

Although Pennsylvania, along with other states, prohibits the literal sale of human tissue, companies that harvest and process tissue can charge for reimbursement of the cost of these services. Such a system allows companies to charge large processing and storage fees that, in practice, amount to highly profitable sales. BTS, for example, received over \$19,117 for the parts from just one body, “Thomas Union” (not a real name). The “procurement” took two cutters an hour; their overhead was a freezer and the cost of shipping. Even if they do not steal, as BTS and the corrupt funeral directors did, procurement companies have a cost of zero for very valuable donated tissue.

Some estimates place the ultimate value of tissue from one body – by the time it is finally sold to a hospital for transplant – at \$100,000. Along with the cost, the number of tissues transplanted per year has exploded. When Michael Mastromarino entered the business, the market for bone grafts alone had already grown six-fold since 1994. In 2003, 1.3 million grafts were distributed for transplantation, according to Robert Rigney, the chief executive officer of the AATB. The market has continued to expand since.

With so much money involved in the tissue trade, unscrupulous practitioners are a near certainty. Moreover, in contrast with human organs, which are strictly regulated by the government and exchanged by a limited number of state-approved nonprofit organizations, human tissue can be harvested and sold by any number of less-regulated

individuals and entities. Some witnesses from within the tissue industry insisted that BTS was an aberration, implying that stricter regulation was not necessary. What BTS and the funeral directors did was indeed extreme, as well as criminal, but it was not a mere fluke. Their offenses were logical and foreseeable outcomes of a legal and infrastructural framework that is unprepared to deal with the volume of tissue being traded, the number of individuals and companies involved in trading it, and the potential profit to be made by corrupt businessmen willing to engage in criminal conspiracies.

FDA regulations

Food and Drug Administration regulations, most recently updated in 2005, aim to assure the safety and efficacy of human tissue for transplantation by requiring: registration of all tissue agencies, donor suitability screening, testing for certain communicable diseases, proper handling and shipping of materials, and monitoring of adverse events. The rules rely largely on transparency, labeling, and tracking to assure safety. A rule that became effective in May 2005 enhances tissue safety by requiring procurers and processors to comply with established “good tissue practices.” However, in light of the huge increase in the volume of tissue processed in recent years, the proliferation of tissue agencies, and the overwhelming task the FDA faces in regulating everything from food to cosmetics, there is still too much vagueness in the regulations, and not enough manpower for adequate oversight.

The FDA registration requirements sound comprehensive: an agency or company cannot legally engage in tissue recovery, processing, storage, labeling, packaging, distribution, or any other process that precedes implantation or research use without

registering with the FDA. Except that to register, one need only provide a name, address, a list of tissues produced or handled, and little else. The application does not ask for any background information on the owners or operators of tissue agencies – not about arrests, or professional misconduct, or qualifications. Thus, Mastromarino – whose license to practice dentistry was suspended first because of drug charges, and then again for practicing without a license – was permitted to register. No inspection of his facilities was required by the FDA before he began operation.

FDA regulations relating to donor eligibility are also lacking. Although it does not matter as much in states such as Pennsylvania, which has its own strong consent law, the FDA regulations do not require verification of consent to donate tissue. Screening is required for certain communicable diseases – HIV, hepatitis B and C, syphilis, and a few of others. But without requirements that actual medical records be reviewed and approved by medical professionals, other diseases that cannot be so easily screened will continue to slip through – as they did with BTS. Despite screening tests that met FDA requirements, RTI and other tissue banks bought and distributed huge amounts of tissue from bodies riddled with bacteria and cancer.

Regulations relating to recovery and handling are sometimes vague and less than comprehensive. The FDA sets no minimum qualifications for those who procure and process human tissue, relying instead on undefined notions of “necessary education, experience, and training.” Medical training is not a requirement, nor is any industry-related certification. Standards specifically covering tissue recovery, as opposed to processing, are contained in one general sentence: it states that tissues must be procured

“in a way that does not cause contamination or cross-contamination during recovery” or otherwise increase the risk of transmitting communicable diseases.

A flaw in FDA regulations that was highlighted by Rigney of the AATB is their failure to set time limits within which tissue must be harvested following death. Rigney testified that it was a 19-hour delay between death and harvesting of tissue that caused the death of a 23-year-old ACL patient in Wisconsin. The tissue banks themselves, in their contracts with BTS and other procurers, set limits on the time between death and harvesting, and these requirements have legal force. But the FDA should not rely on contractual obligations to establish an explicit regime for protecting public health. Surely BTS’s practice of waiting days – in some instances 92 hours, 100 hours, and 113 hours – between death and tissue recovery should be clearly proscribed by federal regulation.

The FDA’s requirements for tracking and labeling are helpful, and important for catching inadvertent errors. They are crucial to the FDA’s basic framework, according to which each agency that handles tissue is responsible for checking that relevant tests have been performed and that the tissue meets all requirements for eligibility. This shared responsibility is intended to add several layers of checks to catch mislabeling, cross-contamination, or fraud. Given how overstretched the FDA regulators are, it is necessary to place considerable responsibility for assuring safety on the companies that do business with each other. However, the fact that BTS escaped notice for three and half years shows that this system has not worked well in certain situations. Danger arises when one link in the processing chain intentionally mislabels and falsifies records, and when other links are less than vigilant in checking the reality behind the documentation.

One reason that the FDA's regulatory system did not detect or deter Mastromarino, Cruceta, McCafferty, and Louis and Gerald Garzone, is that audits and oversight were not well designed to uncover violations caused by outright fraud. Inspections by FDA officials focused largely on whether BTS had established procedures and whether the firm's own logs and paperwork claimed compliance with those procedures. The first inspection was conducted in September 2003. It found that:

- BTS had not "validated" the cleaning procedures used at facilities where human tissue was recovered.
- The firm had not performed weekly and monthly maintenance of the autoclave (an instrument for sterilizing equipment used in tissue recovery).
- During the period from January through August 2003, BTS did not maintain "disposition/destruction" records of human tissue determined to be unfit for transplantation.

These findings were based on a review of BTS's own records and interviews with Mastromarino, Cruceta, and Piccirillo. The FDA accepted Mastromarino's assessment that the recovery locations were "aseptic," without ever visiting them. Knowing that the FDA inspectors lacked the manpower to watch a recovery, or test whether an instrument was sterile, or open a box that supposedly contained tissue to be discarded, Mastromarino simply addressed the identified problems by adjusting his record-keeping. In other words, if BTS in its own documents claimed to be following certain procedures, even though it was lying outright, that was good enough to pass inspection.

When the FDA inspected again in November 2004, the investigator again found that the company had still “not validated cleaning procedures” for the funeral homes. Even so, there was no inspection of those funeral homes. The other record-keeping matters had been cleared up. Never mind that, at that time, BTS was at the height of its fraudulent scheme to steal tissue from decaying bodies in filthy funeral home facilities.

The FDA inspections relied in large part on BTS’s own representations of its procedures. If the lies in the records claimed compliance with regulations, that apparently was sufficient. The FDA’s emphasis on records and tracking is without a doubt useful once a problem is detected: if someone dies following implantation of tainted tissue, for example, FDA-required records would allow the tissue to be traced back to its source. Such records have been crucial to this investigation. The current regulations and inspections are not sufficient, however, to prevent the harm in the first place.

Pennsylvania’s regulation of tissue agencies

Pennsylvania laws plug some of the holes in the FDA’s regulatory scheme. Most importantly, Pennsylvania has a strong donor consent law. The Anatomical Gifts Act (20 Pa. C.S. §8601) requires that donor consent – which the next of kin can give after the donor’s death – be written, or tape-recorded if provided by telephone. The law also sets stringent controls on how, and by whom, tissue may be procured when donors die in hospitals. But the Anatomical Gifts Act was enacted originally in 1968 – the year of the first heart transplant, and long before the proliferation of tissue harvesting. It clearly never envisioned the taking of organs or tissue (except eyes) by anyone other than

doctors in hospitals. Consequently, Pennsylvania laws do not adequately address tissue recovery following deaths that occur outside hospitals.

The state's Anatomical Gift Act, which covers organs and tissue, is very explicit when a donor dies in a hospital: the hospital must immediately notify a designated organ procurement organization. In eastern Pennsylvania, the designated agency is Gift of Life. (The Uniform Anatomical Gift Act sets up a federal scheme, whereby one nonprofit agency – an “organ procurement organization” – is selected for each area of the country to be responsible for handling all organ donations.) The hospital and Gift of Life review a patient's identification, age, cause of death, and medical history to determine eligibility. Then Gift of Life contacts the family for consent to donate, beginning with the spouse and progressing if necessary to the decedent's children, siblings, or guardian, in that order. After obtaining and recording consent, Gift of Life then harvests organs and tissue, distributing the material for transplantation or other uses.

Under the Anatomical Gift Act, Gift of Life is subject to routine oversight by the state. Each of the designated organ and tissue procurement agencies (a second nonprofit group serves western Pennsylvania) must maintain registration with the state to facilitate reviews, audits, and record keeping. The state's Department of Health makes annual death record reviews to ensure that they keep proper records. All of these regulations help assure the safety of tissue taken from those who die in Pennsylvania hospitals.

As originally conceived, the Anatomical Gifts Act explicitly authorizes only surgeons and physicians to perform tissue recovery. (Funeral directors, eye technicians, and medical students who are properly trained and licensed are permitted to recover corneas, but no other tissue.) However, while others are not explicitly authorized, neither

are they clearly prohibited. (20 Pa.C.S.A. §8613(d) states that: “the donee or other person authorized to accept the gift may employ or authorize any surgeon or physician” to carry out the procedure.) Because it seems to assume that all recoveries will be done by doctors in hospitals, the Anatomical Gifts Act neither explicitly limits recoveries to hospitals nor addresses where else they might be performed. The Act has not been updated to reflect the burgeoning tissue business or to address who should perform tissue recoveries and where. Without its own registration requirement for tissue agencies – similar to those in New York, California, and Florida – Pennsylvania cannot assure that those who harvest tissue in the state are qualified and properly screened, or that recovery locations are suitable.

Ironically, in light of what occurred inside the Garzones’ businesses, one of the only places where Pennsylvania law does bar tissue harvesting is in a funeral home’s embalming room. This prohibition derives not from any statute regulating tissue agencies, but from one that covers funeral directors (13 Pa. C.S. §13.186). The Pennsylvania Code states that a funeral home “preparation room may not be used for a purpose other than scientific preparation and embalming of human remains.” The funeral directors, Mastromarino, and Cruceta obviously violated this regulation against misuse of embalming rooms. However, the law as it stands does not address the broader issue of the conflict of interest inherent if funeral home directors were allowed to be involved in the harvesting of tissue from cadavers.

Pennsylvania, like other states, makes it “unlawful for any person to knowingly acquire, receive, transfer or in any way facilitate the transfer for transplantation or other medical therapy any human organ or nonregenerative tissue for valuable consideration”

(35 Pa. C.S. §10025). But the term “valuable consideration” does not include “the reasonable costs associated with the medical evaluation, removal, preservation and transportation,” and there is no standard by which to determine reasonableness.

AATB standards, certification, and accreditation

For years, the American Association of Tissue Banks, a nongovernmental organization, oversaw much of the tissue business with little legislative help. The AATB issues standards that are the most comprehensive guidelines for tissue safety. It also certifies individuals as “Certified Tissue Bank Specialists” and accredits tissue agencies. While the organization’s accreditation is not required for a company to do business, and its rules are not legally enforceable (except when they are incorporated into contractual obligations), the AATB stamp of approval should suggest to those using tissue from accredited tissue banks that companies are being held to a well-articulated standard.

The AATB’s “Standards for Tissue Banking” provide guidelines for the harvesting and storage of human tissue, and outline the requirements for gaining and maintaining accreditation. Within the past several years, some of the AATB standards have been incorporated into federal regulations governing the tissue trade, including the FDA’s Current Good Tissue Practices Final Rule.

The AATB’s standards go beyond the FDA’s regulations in a number of areas – for example, by setting standards for consent, requiring that the medical director of accredited tissue banks be a licensed doctor, and limiting the time period after death when tissue can be recovered. If they were followed by all tissue agencies, AATB standards would go a long way toward assuring tissue safety. Except for those written

into contracts or federal regulations, however, the AATB standards do not have the force of law. They apply only to agencies that voluntarily become accredited. And despite the thoroughness of the standards, AATB-accredited tissue banks distributed large amounts of BTS's tissue while somehow failing to detect the monumental fraud being perpetrated by BTS and the funeral directors.

The AATB, like the FDA, relies in part on tissue banks to provide checks on each other. The AATB requires its accredited agencies to audit the agencies it contracts with and to check their documentation. This system, however, works only as well as the audits that are conducted.

RTI, for example, is an AATB-accredited company. The documentation that it required from BTS (a non-accredited agency) seemed, on its face, to comply with AATB standards. RTI even "audited" BTS, as required by the AATB – visiting BTS's facility in Fort Lee, New Jersey, and checking written procedures and documentation. Yet the RTI auditors never spot-checked to see if a relative consented to donation, or if the doctor listed as the primary care physician really was the doctor of the deceased, or if the blood submitted for testing matched the tissue. They never visited the Philadelphia funeral homes where so much of BTS's tissue was recovered, nor did they ever watch a recovery. They certainly could not have inspected carefully the phony death certificates that BTS provided without noticing that only a tiny portion of the blanks on the forms were filled in. The same is true of all of the tissue banks that accepted BTS tissue.

Robert Rigney, the AATB's CEO, told the Grand Jury that, in light of the revelations about BTS, his organization had appointed a task force to consider whether its

standards needed to be revised. He outlined some of the task force's recommendations that have been implemented:

- The AATB now requires its accredited tissue agencies to include in contracts with any unaccredited agencies provisions that allow the AATB itself to conduct audits of the unaccredited companies. In other words, if BTS (unaccredited by the AATB) did business with RTI (accredited), BTS would have to agree to let the AATB audit it.
- Standards have been revised to require more sharing of medical records and test results among the agencies that handle the tissue.
- Telephone consent by donors must now be recorded, and accredited tissue banks are required to make spot checks to ensure that consents are authentic.
- The updated standards call for expanded services to donor families.

These measures address many, but not all, of the problems brought to light by the funeral directors' and BTS's long-running fraud. Auditing procedures, in particular, still need to be addressed. In addition, actual medical records – prepared by a doctor who has treated the deceased – should be required. (Official death certificates, which the AATB now requires when medical records are unavailable, are helpful, but they do not always list conditions such as HIV and hepatitis if they are not the immediate cause of death.)

State regulation of funeral directors and crematories

Pennsylvania's Funeral Director Law (63 P.S. §479) regulates the licensure and practice of funeral directors and funeral establishments. It also sets up a State Board of Funeral Directors to enforce the law and to “formulate rules and regulations not

inconsistent with this act for the proper conduct of the business or profession of funeral directing and as may be deemed necessary or proper to safeguard the interests of the public and the standards of the profession.”

The failure of the State Board of Funeral Directors (state board) in this case is glaring. To begin with, Louis Garzone’s funeral home was not even licensed between February 2004 and May 2006 when, in response to news stories, the inspector with the Department of State began to investigate the crimes committed there. Had anyone from the state board checked to see if Louis Garzone was operating with a lapsed facility license, they might have noticed the dead bodies piled up in the alley beside his funeral home, or the men toting coolers in and out of the embalming room. Even without unearthing the body-pillaging scheme by its own oversight, once newspapers had revealed what was going on, and the state’s inspector had confirmed it in interviews with the Garzones, surely the board could have penalized the funeral home directors more severely than simply by accepting the voluntary surrender of their licenses. The board has the authority to impose harsh fines for wrongdoing.

What is even more outrageous, the state board and the Commissioner of Professional and Occupational Affairs allowed the Garzones to circumvent even this pathetic penalty. More than a year after they surrendered their licenses, Gerald and Louis Garzone are still operating Garzone Funeral Home, Inc. That they listed their brother who lives in Florida on some paperwork as the “incorporator” of the funeral home is no excuse.

The Funeral Director Law regulates the minutiae of even “student trainees,” requiring them to re-register and pay fees annually and every time they change schools or

mentors. Surely the statute has teeth enough to prevent funeral directors from continuing in their profession after they have used their businesses to commit serious ethical violations and crimes. Meanwhile, the Funeral Director Law does nothing to address the obvious temptation for funeral directors to profit from the bodies brought to them for burial or cremation.

Pennsylvania, moreover, is one of only nine states that do not regulate crematories at all. In Philadelphia, they have to comply with general zoning restrictions and obtain an air pollution construction permit, but that is all. The absence of any licensing body means that, as long as its emissions into the air are kept under control, Liberty Crematory can continue to operate. There is today no regulatory mechanism for shutting down a crematory in the state. This, despite the fact that unsuspecting workers at crematories may be exposed to dangerous body fluids; despite the fact that a crematory can be used to cover up evidence of the illegal taking of body parts; and despite the fact that many grieving families in the Philadelphia area now cannot be certain that the ashes buried or returned to them are even those of their loved ones.

State welfare regulations

Payments made to funeral directors by the Pennsylvania Department of Public Welfare for the funeral costs of assistance recipients are subject to state regulation and to “provider agreements.” The regulations are published at: 55 Pa. Code §285.1-285.4. To become an “eligible provider,” a funeral home must apply for the designation, then sign an agreement with the DPW setting out the provider’s obligations. The fraud perpetrated by the Garzones and McCafferty – charging families full price for funeral services, then billing the state welfare department, without the families knowing, and keeping the \$750

reimbursement for themselves – clearly violated both the state regulations and the terms of their provider agreements. The fact that this criminal behavior went undetected for so long indicates the need for changes in Pennsylvania’s rules and procedures, as well as in the standard agreements for funeral directors designated as eligible providers.

The state regulations detail the procedures to be followed when a welfare recipient dies and his family or other responsible person wants to request assistance to pay for funeral services. At §285.1(a)(1), the regulations state that the request for payment must come from a relative, a friend, a representative of a fraternal society of which the deceased was a member, or a representative of a charitable or religious organization. The regulation explicitly states: “A request for payment will not be accepted from the funeral director, or anyone acting for him.”

In practice, however, this explicit prohibition has been ignored in favor of a confusing caveat in the regulation that states: “The person requesting payment of burial shall apply to the CAO [County Assistance Office]; or, the funeral director may notify the CAO that the person is requesting payment of burial.”

In Philadelphia, the county assistance office, in effect, let the funeral directors request payment. The CAO routinely mailed the “Request for Burial Payment” forms – so-called PA118s – to the Garzones and McCafferty and then received them back from the funeral directors. The funeral directors filled out the forms stating that they had received no payments toward a funeral, either from the family for small extra items or services, or from insurance policies or accounts of the deceased. The only participation by the next of kin was to sign the PA118 form. In 49 cases in which it has been

established that family members' signatures were forged, the funeral directors did not even perform this obligation.

The PA118 form does provide a possible check on abuse by funeral directors by requiring a witness to the family member's signature – except that funeral directors are permitted to act as that witness. In the 49 Philadelphia forgery cases, the funeral directors merely bore witness to their own forgeries. Even in situations where family members identified their signatures on the PA118 form, they reported that the funeral directors deceived them regarding what they were signing. None of them knew they were requesting payment from the state welfare department for their relatives' funerals. Nor were they aware that the Garzones or McCafferty were requesting payment from the state. The families themselves had, in almost every case, already paid in full for the funerals.

Because the state welfare officials routinely deal with – and disburse payments to – the funeral directors rather than the relatives of the deceased, another consequence is that family members may not know they are entitled to assistance for funeral services. This certainly was the case among the families contracting with the Garzones and McCafferty. By allowing funeral directors to handle so much of the paperwork, and by leaving the families out of the loop, the state procedures made it easier for the funeral directors' to get away with their fraud.

Family members interviewed by the state Inspector General's agent described the hardship of paying for their loved ones' funerals. Even though the funeral directors' agreements with the DPW prohibit them from billing anyone for funeral services for welfare recipients, in none of these cases did the three directors inform the families that

the funerals could be paid for by the state. By concealing this information, the funeral directors were able to charge the families as well as bill the state for the services. A witness with the welfare department told the Grand Jury that funeral directors have a duty to inform families who are eligible for assistance. (They obviously have a duty if they are asking a family member to sign a form requesting burial payment from the DPW.) But this obligation needs to be made more explicit in the regulations and provider agreements, and there need to be clear and effective procedures for enforcing it.

The regulations do contain a potential safeguard, specifically designed to prevent funeral directors from double billing. Section 285.4(d) states: “When the county office receives notice that the funeral director has been paid, it will send a letter to the person who requested burial payment if he is a relative of the deceased....The letter is aimed at preventing duplication of burial payment.” The rule even provides a sample letter. To be an effective check, this letter must be mailed directly to the next of kin, not to the funeral director.

The Grand Jury heard testimony from witnesses from the DPW who believe that procedures followed in the Philadelphia county assistance office may have contributed to problems in processing welfare burial payments. Once it has determined that a deceased person was eligible for assistance, the local CAO is charged with checking to see what other resources are available to pay for burial. These can include life insurance, burial reserves, veteran benefits, and other sources. In most county assistance offices in the state, the PA118 form is processed by an “income maintenance caseworker,” who has access to this information. In Philadelphia, a clerk was responsible for filling out the CAO’s portion of the PA118, which determined the deceased recipient’s eligibility for

burial payments. The problem, according to the witnesses, is that a clerk does not have the authority to determine eligibility for burial payment. Welfare administrators suggested that it was a better practice to have the PA118 processed by income maintenance caseworkers at the CAO. Since the Grand Jury began investigating the Garzones and McCafferty's welfare fraud, the Philadelphia county assistance office has changed its procedures.

Finally, the investigation into the fraud perpetrated by the Garzones and McCafferty revealed that the state's welfare department does not require eligible providers to renew their provider agreements – ever. Even though provider agreements are not transferable, and for tax purposes are tied to an individual's social security or tax ID number, Gerald Garzone was requesting burial payments based on his brother James Garzone's provider number. The provider agreement had been signed nearly 20 years ago – in 1987.

While the Grand Jury has identified ways in which the procedures for processing requests for welfare burial payments can be improved to make the program less susceptible to fraud, it does not mean to suggest that the procedures were in any way responsible for the crimes committed by the Garzones and McCafferty. The three Philadelphia funeral directors stole from the DPW by forging signatures and lying on the PA118 forms – falsely claiming that they had not been paid for funeral services. Their crimes were blatant and clearly prohibited by law.

RECOMMENDATIONS OF THE GRAND JURY

Based on all the evidence presented to us, and our analysis of that evidence – including thousands of documents and testimony from investigators, expert witnesses, government workers, and people in the funeral and tissue businesses – the Grand Jury makes the following recommendations:

1. Prosecute to the fullest extent possible Louis Garzone, Gerald Garzone, James McCafferty, Michael Mastromarino, Lee Cruceta, and the corporations, Garzone Funeral Home, Inc., and Liberty Cremation, Inc.

The indictments should include first degree felony charges for operating a corrupt organization in violation of 18 Pa. C.S.A. §911. The Grand Jury has issued a presentment describing clear and flagrant defiance of Pennsylvania laws and has recommended that criminal charges be filed by the Philadelphia District Attorney's office.

Federal authorities should further investigate to determine if additional federal charges are warranted. This criminal enterprise reached across the nation and the world, as did its victims. It involved entities in numerous states and violations of Food and Drug Administration regulations. Multiple companies were set up by the body cutters to shelter their earnings. There is much still to investigate and prosecute that is beyond the scope of a Philadelphia grand jury.

2. Prohibit funeral homes from performing tissue recovery.

The Pennsylvania legislature should amend the Anatomical Gift Act and the Funeral Director Law to prohibit recovery of tissue in funeral homes. In New Jersey, the

State Board of Mortuary Science has proposed such a ban. Funeral homes are inappropriate settings because of the inherent conflict of interest for their owners, and because they are not appropriately sterile and equipped medical facilities. Since it is not easy for most people to gain access to cadavers, this reform would go a long way toward ending the theft of body parts in Pennsylvania.

3. Make theft of body parts a distinct felony crime.

The Pennsylvania legislature should amend the Crimes Code to send an unmistakable message to society that stealing body parts from the dead is an extremely serious offense, and not one that can be graded according to a dollar figure. A section should be added to theft offenses in state law making it a felony to steal any part of a human corpse.

4. Require all tissue agencies to be licensed by the state and accredited by the American Association of Tissue Banks.

Pennsylvania should require that all tissue procurement and processing agencies operating in the state be licensed by the state. Requirements for a license should include a background check on the principals – including for arrests, professional misconduct, character, and technical competence. All facilities should be inspected before approval. Accreditation by the American Association of Tissue Banks should be required for a license. This would automatically subject the agencies to the most comprehensive standards for safe tissue practices, including qualifications and training of staff, procedures for donor consent, and donor eligibility screening by medical professionals.

The AATB could make its accreditation even more valuable if it required all of its agencies to deal only with other AATB-accredited facilities. BTS proved that one unaccredited agency that does not abide by the rules and provides false information to other organizations in the processing chain can present a danger to society.

5. Strengthen auditing practices of the AATB, the FDA, and tissue agencies.

Auditing practices by all parties need to reflect the reality that fraud and criminal behavior are to be expected in a business involving so much money – even a business with a noble purpose – especially when profits can be greatly enhanced by cutting corners. Audits cannot merely check records and written protocols or rely on self-reporting. Audits of tissue agencies by the Food and Drug Administration, the AATB, and AATB-certified tissue banks (which are required by the AATB to audit facilities with which they do business) must include spot checking to verify donor consent, medical records, and blood samples submitted for screening – to make sure they are legitimate and match the tissue being distributed. Inspectors should visit all facilities where tissue is procured and processed. They need to observe procedures being performed. They should also demand actual medical records for any donor – not just interviews with someone claiming to be familiar with the donor’s health history. The AATB is reportedly working on amendments to its procedures to address the problems revealed by BTS’s fraud. While taking steps to require that all tissue agencies operating in the state be AATB-certified, Pennsylvania officials should seek assurance that the association’s auditing procedures are effective and routinely utilized.

6. Consider requiring that all tissue recovery be coordinated through a designated Organ Procurement Organization, such as Gift of Life, for non-hospital deaths as well as hospital deaths.

Gift of life, the federally designated organ procurement organization in the Philadelphia area, is already inspected and audited by the Pennsylvania health department. It has a proven track record for sound tissue practices and excellent donor services. Coordinating through one agency would avoid the possibility that grieving families might be hounded by several different recovery operators. Pennsylvania's Anatomical Gift Act could be amended to require, in cases where death occurs outside of a hospital, that funeral directors and coroners refer any families interested in tissue donation to the federally designated organ procurement organization in their area.

7. Define "reasonable costs" that tissue banks are permitted to charge without violating prohibitions against buying and selling human tissue.

Pennsylvania's law prohibiting the sale of human tissue is meaningless in practice if there are no limits to the amount that agencies and companies can charge at each step of the process from procurement of tissue to implantation. If Pennsylvania implements the Grand Jury's fourth recommendation and begins to license tissue banks, then the licensing body should also be assigned the task of defining more precisely what are reasonable costs. Limiting the profits available to truly reasonable costs would make the tissue business less appealing to those who are simply looking for large profits.

8. Review policies of the Bureau of Professional and Occupational Affairs that permitted Louis and Gerald Garzone to continue operating their funeral homes.

As the Grand Jury was concluding its investigation of the body harvesting enterprise operated by the Garzones, McCafferty, Mastromarino, and Cruceta, it learned that the Garzones are still operating their funeral homes, based on an obvious sham, after they voluntarily surrendered their funeral director licenses.

The State Board of Funeral Directors, which is part of the Bureau of Professional and Occupational Affairs, has allowed these men who so badly abused their positions as funeral directors to stay in business, after they made a show of surrendering their licenses, simply by putting their brother's name on a second set of articles of incorporation for "Garzone Funeral Home, Inc." (Louis Garzone is listed as the incorporator and sole shareholder on the first set of incorporation papers.) The Pennsylvania Inspector General should investigate how the Garzones were able to get a new license and why they have been permitted to continue in business.

9. Improve oversight of funeral homes to serve the public's welfare.

The emphasis of Pennsylvania's Funeral Directors Law, related regulations, and the State Board's enforcement of them should be to promote public welfare and safety. The point of licensing should be to assure the public that funeral homes in the state are operated in an ethical, competent, and sanitary manner. Both the content of the law and the manner of its enforcement should better reflect these goals, even though the vast majority of funeral directors are doubtless ethical and law-abiding. The Funeral Directors Law itself is filled with arcane rules about names of facilities, widows inheriting licenses,

and registration of interns, but little about serving the public. The regulations devote only a few sentences to sanitation.

Inspections, oversight, and disciplinary action should focus on issues relating to public welfare – issues such as dishonest dealings with clients, bodies being left in alleys outside funeral homes, filthy embalming rooms, and improper disposal of infected body fluids. Unannounced inspections should be routine. And lapsed licenses should be investigated.

10. Begin regulating crematories.

Pennsylvania should join the vast majority of states that regulate crematories. The wrongdoing of Liberty Crematory and its owners, James McCafferty and Louis and Gerald Garzone, demonstrates the potential for unethical and unsafe practices in the crematory business. The appropriateness of a crematory business in a residential neighborhood should also be reconsidered.

Some misdeeds, such as Liberty's, are criminal and can be sanctioned by law enforcement. But others, like lack of care in identifying bodies, sloppy practices that expose workers to dangerous body fluids, and poor record keeping, are not expressly prohibited by state law or currently subject to regulatory oversight. That needs to change.

11. Amend procedures for requesting burial payments for welfare recipients.

Pennsylvania regulations clearly intend that requests for burial payments for welfare recipients come from relatives of the deceased, and not from funeral directors. Yet, in practice, officials within the system have allowed funeral directors to wrench

control of the request process from family members, thus easing the way for fraud such as that perpetrated by the Garzones and McCafferty. The Pennsylvania code should be amended to remove the sentence in §285.1(a)(1) that allows funeral directors to notify county assistance offices that a client is requesting welfare benefits. The DPW should revise the application itself – the PA118 form – so that control of the request would be removed from the funeral directors and placed with the families. The Pennsylvania Office of Inspector General, which conducted the investigation into welfare fraud committed by the Garzones and McCafferty, should advise the DPW on these revisions.

The Grand Jury also urges that all County Assistance Offices be directed to comply with the existing requirement under §285.4(d) that a follow-up letter be sent to families notifying them that the funeral director has been paid.

12. Enforce the state regulation forbidding funeral directors from charging families of welfare recipients for the cost of basic funeral services.

By agreeing to provide funeral services to those eligible for welfare assistance, and in return for payment by the state of \$750, funeral directors are forbidden to charge anyone else any amount for the cost of basic funeral services. They may only accept small contributions for extras such as flowers and religious services. The welfare department should enforce this regulation. At the same time, it should consider raising the \$750 reimbursement so that more funeral directors will be willing to provide funeral services to the poor.

13. Require funeral directors to renew registration as welfare providers every five years.

The procedures for reviewing the eligibility of funeral directors as providers for the welfare department should be revised to include a requirement that registration be renewed every five years. To aid this review process, funeral directors should be required to immediately report – to the Department of State and to the DPW – any disciplinary action taken by a state or federal agency against them or their businesses.

14. Take steps to ensure that funeral home clients are informed about the welfare department's burial payment benefit.

Welfare regulations should be amended to explicitly require funeral directors who are registered as “eligible providers” to inform customers that the state will pay for the funeral costs of those eligible for public assistance. This requirement should also be spelled out in the provider agreements signed by the funeral directors. The DPW should produce and distribute a brochure to institutions that care for the indigent explaining the department's burial benefit. If more people are made aware that this benefit is available, it will be more difficult for corrupt funeral directors to cheat them.

APPENDIX

In order to sell diseased, decayed, and mishandled tissue, the conspirators had to falsify and forge documentation designed to protect the public from dangerously infected implants. Federal regulations and contractual obligations with tissue banks required Biomedical Tissue Services (BTS) to provide for each body:

- a consent form from next of kin to donate the tissue;
- a social and medical history taken from the next of kin;
- a medical history obtained by interviewing the physician of the deceased;
- a serology report testing the donor's blood for several contagious diseases (including HIV and hepatitis);
- a recovery report documenting the circumstances – including time, place, and participants – of the tissue recovery;
- medical records from the health care facility where the person died (if death occurred in a hospital or other medical facility);
- a form describing the circumstances of death (if the death occurred outside of a hospital);
- a physical assessment of the donor; and
- checklists of procedures relating to the sterilization of instruments and sanitation at the recovery site.

The documents sent by Biomedical Tissue Services to the tissue banks along with Joseph Pace's tissue are attached as an appendix. These are typical of the documents that accompanied all 244 of the bodies harvested in Philadelphia.

**BIOMEDICAL TISSUE SERVICES
CONSENT FOR DONATION OF ANATOMICAL GIFTS**

Print all information except where signature is indicated.

I, the undersigned, as the next of kin, or guardian of JOSEPH PACE (donor's name), certify that I am at least 18 years of age and related to the above named donor as follows:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Spouse | <input type="checkbox"/> Grandparent |
| <input type="checkbox"/> Adult son or daughter | <input type="checkbox"/> Guardian of the person at the time of his/her death |
| <input type="checkbox"/> Either parent | <input type="checkbox"/> Representative ad litem |
| <input type="checkbox"/> Adult brother or sister | <input type="checkbox"/> Other _____ |

At the time of execution of this document, having no notice that this gift would have been opposed by the donor, I do hereby consent to the removal of the following tissue(s) by the staff of Biomedical Tissue Services:

TISSUE/BONE:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Corticocancellous Iliac Bone | <input type="checkbox"/> Ribs/Costal Cartilage |
| <input checked="" type="checkbox"/> Bones (Upper Extremities, Soft Tissue & Supporting Structures) | <input checked="" type="checkbox"/> Skin |
| <input checked="" type="checkbox"/> Bones (Lower Extremities, Soft Tissue & Supporting Structures) | <input type="checkbox"/> Spine |
| <input type="checkbox"/> Heart Valves/Pericardium | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Blood Vessels | |

Medical Research Yes No Telephone Consent Yes No

To assure medical acceptability of the tissues for transplantation, I consent to the removal of blood and tissue samples for laboratory testing including, but not limited to, blood typing, viral hepatitis, syphilis and HIV. Human tissue samples may include organ biopsies, lymph nodes, blood and cultures. I authorize the recovery agencies to obtain any needed medical information including, but not limited to, medical records and autopsy reports. I authorize the Medical Examiner's Office / Coroner's Office / Health Care Facility / Funeral Director to release the remains and autopsy report of the above named person to the recovery representative.

Protect the confidentiality of tissues donated for transplantation/research - Biomedical Tissue Services will not release any personal, identifiable information of any kind to a third party from tissues that have been procured, except upon the written consent of the donor or the person authorized by law to make the donation, or to authorized employees of the department, or as permitted by law.

I have been advised that the costs directly related to evaluation, recovery, preservation and placement of tissues will not be charged to the family. I have been offered information about the tissue recovery procedure, its impact on burial arrangements and the appearance of the donor.

I understand the gift may have a broad range of reconstruction and cosmetic applications that the possibility exists that the gift may be transported abroad. I have been offered information on how the gift is prepared and placed for transplantation and that non-profit and for-profit organizations may be involved in the facilitating of the gift.

CONSENTING LEGAL NEXT OF KIN	<u>LINDA PACE</u> NAME, PRINTED	<u>11/26/05</u> DATE
RELATIONSHIP TO DECEDENT	<u>SPOUSE</u> RELATIONSHIP TO DECEDENT	<u>PHILADELPHIA</u> CITY
STATE	<u>PA</u> STATE	<u>215-549-8780</u> PHONE
WITNESS (SIGNED)	<u>[Signature]</u> WITNESS (SIGNED)	<u>11/24/05</u> DATE
WITNESS (SIGNED)	<u>[Signature]</u> WITNESS (SIGNED)	<u>11/26/05</u> DATE
	<u>2430 4TH ST.</u> ADDRESS	
	<u>19132</u> ZIP CODE	
	<u>RICHARD BIFONE</u> WITNESS (PRINTED)	
	<u>[Signature]</u> WITNESS (PRINTED)	

BIOMEDICAL TISSUE SERVICES
Rev. 2 5/1/04

000076

CONSENT FOR DONATION OF ANATOMICAL GIFTS FORM
FORM F200-001

Consent form signed by Michael Mastromarino and Richard Bifone. They purport to witness a spouse's consent to donate Joseph Pace's body parts. The alleged spouse, "Linda Pace," is not a real person. Mastromarino had Bifone sign stacks of blank consent forms and would fill the names in later.

Biomedical Tissue Services, Ltd.
 2125 Center Avenue, Suite 300
 Fort Lee, New Jersey 07024

MEDICAL SOCIAL HISTORY INTERVIEW

Interview Date 1/26/05 Interview Time (Military) 22:10

Do you feel that you have sufficient knowledge of the donor to answer questions regarding this medical/social history interview? Yes No

Interviewees PACE LINDA
 Last MI First Last MI First

Address 2430 4th ST
 City/State/Zip PHILA, PA - 19133
 Telephone No. 215-549-8780

Relationship to Donor: Spouse Adult Brother or Sister
 Adult Son or Daughter Guardian at Time of Death
 Either Parent Other Authorized Person (Specify)

Name of person conducting interview MICHAEL MASTROMARINO
 First Last

Title of person conducting interview TISSUE BANK DIRECTOR

Signature of person conducting interview D. M. Mastromarino

Donor's Primary Care Physician or Clinic Dr. Hixson

Address of Primary Care Physician or Clinic PHILA, PA

Telephone No. of Primary Care Physician or Clinic 215-679-9037

We are about to proceed with the medical social history questionnaire. I have about 40 questions and this interview should take about 20 minutes.

	AGENCY NAME	OTPO #	INTERVIEWER INITIALS
Medical and Social Donor Evaluation Questionnaire	BIOMEDICAL TISSUE SERVICES	0805-A126	mm
	DONOR NAME		GENDER
	Last <u>PACE</u> First <u>JOSEPH</u>	AGE <u>54</u>	<u>MALE</u>

BIOMEDICAL TISSUE SERVICES
 Rev. 4/12/01/04

000077

MEDICAL/SOCIAL HISTORY INTERVIEW
 FORM F200-002

Mastromarino falsely certified that he interviewed "Linda Pace" (the non-existent spouse) about Joseph Pace's medical and social history. The primary care physician listed, "Dr. Hixson," is also fabricated.

List any known surgical procedures donor has undergone in their lifetime; please list procedures, procedure date, physician, and hospital or clinic.

Constrastulmonary - 02 - no postop complications

(B) Temporal Bone Fr - slip Trans - 97 - no

1. Has the deceased ever tested positive for viral Hepatitis B or Hepatitis C OR had close contact with anyone (living in same household, sharing kitchen utensils) in the last 12 months who was diagnosed with viral hepatitis? Yes No
2. Did the deceased have a tattoo, ear or other body piercing or acupuncture in the past 12 months in which shared instruments are known to have been used? Yes No
3. Has the deceased ever been diagnosed with Creutzfeldt-Jakob Disease (CJD) or is there any history of a blood relative with CJD? Yes No
4. Did the deceased ever receive a dura mater transplant? Yes No
Any organ, tissue or corneal transplants? Yes No
Transplant _____ Transplant Date _____
5. Did the deceased have active tuberculosis within the past 12 months? Yes No
6. Did the deceased have any evidence or history of an autoimmune disease (i.e. Systemic Lupus, Rheumatoid Arthritis, Sarcoidosis, Polyarteritis Nodosa or Scleroderma)? Yes No
7. Was the deceased ever given human-derived pituitary growth hormone? Yes No
8. Has the deceased ever received human-derived clotting factor concentrates for hemophilia or related clotting disorders? Yes No
9. Has the deceased ever had a positive test for HIV? Yes No
10. In the past 12 months, has the deceased been diagnosed with or treated for any sexually transmitted diseases such as syphilis or gonorrhea? Yes No

Medical and Social Donor Evaluation Questionnaire	AGENCY NAME		OTPO #	INTERVIEWER INITIALS
	BIOMEDICAL TISSUE SERVICES		BMO5-A126	mm
DONOR NAME		AGE	GENDER	
Last PACE	First JOSEPH	54	MALE	

BIOMEDICAL TISSUE SERVICES
Rev. 4/12/01/04

000078

MEDICAL/SOCIAL HISTORY INTERVIEW
FORM F200-002

Mastromarino had his employees mark "no" boxes on blank medical/social history forms. Contrary to the answers on Nos. 1 and 9, Pace had tested positive for both hepatitis C and HIV.

SOCIAL HISTORY INFORMATION

11. Has the deceased been sexually active with a male or female in the past five years? *If the answer to Question 12 is "No" then Question 13 can be omitted.* Yes No

12. a. Has the deceased had sex with someone who had received human-derived clotting factor concentrates in the past 12 months? Yes No

b. MALE: To the best of your knowledge, has the deceased had sex with another male in the last five years? Yes No

FEMALE: Within the last 12 months, has the deceased had sex with a male who had sex with another male? Yes No

c. Has the deceased engaged in sex in exchange for money or drugs in the past five years or ever had sex with anyone who has? Yes No

d. Has the deceased had sex in the past 12 months with any person known or suspected to have Hepatitis B or C, or infected with HIV? Yes No

e. Has the deceased been sexually active with anyone who has been incarcerated in jail or a correctional facility for 72 consecutive hours or longer in the past 12 months?
Incarceration Facility _____ Incarceration Date _____

f. In the past five years, has the deceased been sexually active with anyone who has used a needle for self-injection of drugs for anything other than medical purposes? Yes No

13. Was the deceased an inmate of a jail or correctional facility for more than 72 consecutive hours in the past 12 months? Yes No

Incarceration Facility _____ Incarceration Date _____

14. The following questions (a-f) are related to possible signs and symptoms of HIV and viral Hepatitis B and C infection.

a. Has the deceased exhibited unexplained systems such as: nausea, vomiting, persistent diarrhea or fever >100.5° for greater than 10 days? Yes No

b. Unexplained persistent cough, shortness of breath, opportunistic infection, or lymphadenopathy (swollen lymph nodes) lasting greater than one month? Yes No

c. Demonstrated blue spots on the skin or mucous membranes typical of Kaposi's sarcoma? Yes No

d. Unexplained hepatomegaly (enlarged liver) or yellow jaundice? Yes No

e. Unexplained night sweats? Yes No

f. Has the deceased experienced any periods of unexplained weight loss? Yes No

Medical and Social Donor Evaluation Questionnaire	AGENCY NAME		OTPO #	INTERVIEWER INITIALS
	BIOMEDICAL TISSUE SERVICES		DM05-A126	MM
DONOR NAME		AGE	GENDER	
Last	First	54	MALE	
PACE		JOSEPH		

BIOMEDICAL TISSUE SERVICES
Rev. 4 12/01/04

MEDICAL/SOCIAL HISTORY INTERVIEW
FORM F200-002

000079

15. In the past five years, has the deceased used a needle to inject drugs into their veins, muscles or under their skin for non-medical use?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
16. In the past year has the donor used cocaine?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
17. Was the deceased exposed to known or suspected viral Hepatitis or HIV infected blood through an accidental needle stick or through contact with an open wound, non-intact skin or mucous membrane in the past 12 months?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
18. Was the deceased vaccinated for smallpox within the last 21 days?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
19. Did the deceased exhibit any reactions to smallpox within the last eight weeks, such as cloudy blisters, sores or scabs?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
20. Had the deceased been in close contact (i.e. touching a vaccination site, touching coverings of a vaccination site, handling bedding that has been in contact with an uncovered vaccination site, or physical intimacy) with anyone receiving the smallpox vaccination and exhibited signs and symptoms of smallpox within the last eight weeks?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
21. Has the deceased been diagnosed with encephalitis or meningitis of a viral or unknown nature such as West Nile Virus in the last 28 days? <i>Physician Name</i> _____ <i>Diagnosis Date</i> _____	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
22. Did the donor spend three or more consecutive months in the United Kingdom from the beginning of 1980 through the end of 1996? (If yes, list dates/durations.) Explain _____	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
23. Did the donor cumulatively live in Europe for a total of five years or more between 1980 and the present (this time includes time spent in the UK from 1980 through 1996)? (If yes, list dates/durations.) Explain _____	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
24. Was the donor a current or former U.S. military member, civilian military employee, or dependent of a military member or civilian employee who resided at U.S. military bases in: a) Northern Europe (Germany, United Kingdom, Belgium, and the Netherlands) six consecutive months or more from 1980 through 1990? OR b) Elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) six consecutive months or more from 1980 through 1996?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Medical and Social Donor Evaluation Questionnaire	AGENCY NAME	OTPO #	INTERVIEWER INITIALS
	BIOMEDICAL TISSUE SERVICES	BM05-A126	mm
	DONOR NAME	AGE	GENDER
Last	First	AGE	GENDER
FACE	JOSEPH	54	MALE

BIOMEDICAL TISSUE SERVICES
Rev. 4 12/01/04

MEDICAL/SOCIAL HISTORY INTERVIEW
FORM F200-002

000080

25. Did the donor receive any transfusion of blood or blood components in the United Kingdom between 1980 and the present? Yes No

26. Did the donor receive bovine insulin injections between 1980 and the present (product was not manufactured after 1980)? Yes No

PEDIATRIC DONORS (18 MONTHS OF AGE OR LESS)

27. Was the birth mother of the child diagnosed with or at risk for HIV, Hepatitis B or Hepatitis C? Yes No
N/A

28. Was the child breast-fed in the past 12 months by anyone diagnosed with or at risk for HIV, Hepatitis B or Hepatitis C? Yes No
N/A

ADDENDUM QUESTIONS

The Addendum Questions are intended for the purpose of providing more information to the Medical Director. "Yes" answers in this section do not necessarily rule out tissue donation. Final determination of suitability shall be left to the discretion of the Medical Director.

1. Is there a history of glaucoma, cataract surgery, corneal disease, retinoblastoma, diabetic eye disease, tumors in or near the eyes, eye surgery including refractive procedure known as LASIK, or recent infections or inflammations of the eye? (Please list treating physician and dates.) Yes No
Explain _____

2. Did the deceased have a history of cancer (i.e. malignant tumors or leukemia)? (Please types of cancer, types of treatments, treating physician and dates.) Yes No
Explain _____

3. Has the deceased ever been treated for an exposure to a toxic substance, such as lead, mercury or pesticides? (Please list involved dates and type of agent.) Yes No
Explain _____

4. Has the deceased ever been exposed to rabies or exhibited bites from bats, skunks, dogs or other unknown animals? Yes No

5. Has the deceased ever traveled to or resided in a foreign country? (If yes, indicate name of country and dates.) Yes No
Explain _____

Medical and Social Donor Evaluation Questionnaire	AGENCY NAME		OTPO #	INTERVIEWER INITIALS
	BIOMEDICAL TISSUE SERVICES		BM05-4126	mm
	DONOR NAME		AGE	GENDER
	Last PACE	First JOSEPH	54	MALE

BIOMEDICAL TISSUE SERVICES
Rev. 4 12/01/04

MEDICAL/SOCIAL HISTORY INTERVIEW
FORM F200-002

000081

Joseph Pace was diagnosed with cancer of the larynx. Mastromarino provided a false answer in response to Question No. 2.

6. Was the deceased ever diagnosed with or treated for malaria in the last three years or travel to a malarially endemic area within the last six months? (If yes, list dates and treating physician, or area visited.)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Explain _____				
7. In the past 12 months, did the deceased have any significant infectious disease, i.e. fungal infections, Epstein Barr Virus, Bacterial Endocarditis or Pyelonephritis? (If yes, indicate disease and dates.)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Explain _____				
8. Did the deceased smoke cigarettes? (If yes, indicate number of packs per day and for how long.)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No		
Explain <u>up to 1 pcp</u>				
9. Did the deceased drink alcohol? (If yes, indicate type of alcohol, amount and how often.)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No		
Explain <u>moderate amount</u>				
10. Did the deceased have any evidence or history of insulin dependent diabetes?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
11. Did the deceased suffer from any type of neurologic or brain disease such as Alzheimer's, Multiple Sclerosis, dementia, meningitis, encephalitis, ALS, periods of confusion, recent memory loss or seizures? (If yes, explain.)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Explain _____				
12. Has the deceased been diagnosed with or treated for Chagas' disease? (If yes, list treating physician and date.)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Explain _____				
13. Has the deceased ever been diagnosed with any type of heart disease or cardiac infections? (If yes, list disease, treating physician and dates.)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No		
Explain <u>CAD, HTN</u>				
14. Does the deceased have a history of varicose veins, phlebitis, deep vein thrombosis, poor circulation or muscular dystrophy? (If yes, list disease, treating physician and dates.)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Explain _____				
Medical and Social Donor Evaluation Questionnaire	AGENCY NAME		OTPO #	INTERVIEWER INITIALS
	BIOMEDICAL TISSUE SERVICES		BIMOS-A126	MM
	DONOR NAME		AGE	GENDER
	Last <u>PAGE</u>	First <u>JOSEPH</u>	<u>54</u>	<u>MALE</u>

BIOMEDICAL TISSUE SERVICES
Rev. 4/12/01/04

000082

MEDICAL/SOCIAL HISTORY INTERVIEW
FORM F200-002

Mastromarino provided some "yes" answers to questions on the medical/social history form. For example, he often represented that the deceased had smoked up to one pack of cigarettes per day, or was a moderate drinker. These answers were in all cases fabricated.

Biomedical Tissue Services
2125 Center Avenue, Suite 300
Fort Lee, New Jersey 07024

Certifying Physician Interview Form

Physician Name (or designee): D. I. [unclear] Tele. No.: 215-649-9037
Donor Name: JOSEPH PACE Donor No.: EM05-A126

To the best of your knowledge, did this patient have a history or presence of:

- | | | |
|--|-----------|-------------|
| 1. Severe chronic infections | Yes _____ | No <u>X</u> |
| 2. Serious chronic inflammatory disease | Yes _____ | No <u>X</u> |
| 3. Autoimmune disease | Yes _____ | No <u>X</u> |
| 4. IV drug abuse within the last 5 years | Yes _____ | No <u>X</u> |
| 5. Cancer | Yes _____ | No <u>X</u> |
| 6. HIV (Infections or high risk behavior) | Yes _____ | No <u>X</u> |
| 7. Hepatitis | Yes _____ | No <u>X</u> |
| 8. Are you aware of any reason the patient should not be a musculoskeletal tissue donor? | Yes _____ | No <u>X</u> |

Certifying physician interview (or designee): PT is a 54 y.o. male.
Review of past medical hx w/ no Hx - car, slip on stairs/steering
PT also has no known PT hist seen in physician office over
his age - prior to death it noted to be A to F, no evidence of
lymphadenopathy, jaundice, or flu-like symptoms. Review of med / soc, and
physical assessment no other factors for communicable disease noted.
No Contra-Indications to Recover Tissue. Secondary / culture pending

Based on the information provided in the medical social history interview, the certifying physician interview provided above, and the donor suitability criteria as established in SOP 200-020 and the current AATB Standards, this donor is suitable for surgical recovery.

Information Reviewed By:
Signature: D. I. [unclear] Date: 2/4/05

Mastromarino sent tissue banks this fraudulent form, which purports to represent an interview with Pace’s physician. On the form, Mastromarino indicates falsely that Pace had no known history of cancer, HIV, or hepatitis and that there are no “contra-indications to recover tissue.”



BM05-A126

**BioMedical
Services Report**

Primary ID: BM05A126 Reference ID: Order ID: 44362
 Age: 54 Reference ID:
 Requesting Inst: Biomedical Tissue Services Sex: Male
 Date In Lab: 28-Jan-05 Req. Physician: Herman Baer, M.D.
 Report Status: Final Date Reported: 30-Jan-05

Testing Results

Specimen ID	Collected	Test Name	Result	Reference Range
LT-02	1/27/2005 at 7:50	Blood Typing	O Positive	
TT-01	1/27/2005 at 7:50	HBcAb(IgM)	Negative	Negative
TT-01	1/27/2005 at 7:50	HBsAg3.0	Negative	Negative
TT-01	1/27/2005 at 7:50	HCV 3.0	Negative	Negative
LT-02	1/27/2005 at 7:50	HIV/HCV NAT	Negative	Negative
TT-01	1/27/2005 at 7:50	HIV1/2 Ab PLUS O Peptide	Negative	Negative
TT-01	1/27/2005 at 7:50	HTLV I&II Antibody	Negative	Negative
TT-01	1/27/2005 at 7:50	RPR	Negative	Negative

*For investigational use only. Not for use in diagnostic procedures.

For reporting purposes: Negative is equivalent to Non-Reactive and Positive is equivalent to Reactive.

<< >> indicates a critical result.

This information has been disclosed to you from records whose confidentiality is protected by State law. State laws prohibit further disclosure without permission from Regeneration Technologies, Inc..

Technologist: C. Stallone Date: 1/30/05
 Herman Baer, M.D. Medical Director

000084

42570

11621 Research Circle • Alachua, Florida 32815 • Fax: 386.462.9576
 Customer Service 1.877.737.7858

Regeneration Technologies, Inc. tested blood identified by Lee Cruceta as having been drawn from Joseph Pace. The serology report shows that the blood sample was not infected by HIV or hepatitis, even though Pace had both. The Grand Jury found many instances in which the blood sample submitted by Cruceta did not come from the supposed donor.

AN INFUSION SUMMARY FOR _____ MUST BE COMPLETED ON ALL BLOOD SPECIMENS USED FOR DISEASE MARKER TESTING.

SAMPLE INFORMATION

**Print all information except where signature is indicated.*

Blood Draw Date: 1/27/05 Date of Death: 1/26/05
 Blood Draw Time: 07:50 Time of Death: 13:30
 Recovery Sample Hospital Sample OPO Sample Eye/Skin Bank Sample

Donor Weight in kilograms (2.2 lbs = 1 kg): 180 lbs = 81.8 kg

Plasma Volume (PV)
 Total Plasma Volume = Donor Weight (kg) divided by .025 PV = 3272

Blood Volume (BV)
 Total Blood Volume = Donor Weight (kg) divided by .015 BV = 5453

A. Total Volume of Blood Products Infused / 48 Hours (PRBCs, Whole Blood, Reconstituted Blood Products)

Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>

Total Volume of Blood Products Infused: "A" = 0

B. Total Volume of Colloids Infused / 48 Hours (FFP, Platelets, Albumin, Dextran, Hetastarch)

Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>

Total Volume of Blood Colloids Infused: "B" = 0

C. Total Volume of Crystalloids Infused / 1 Hour (Normal Saline, Lactated Ringers, Dextrose in Water)

Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>
Product	Amount	ml	Date/Time Infused:	<u>/</u>

Total Volume of Blood Crystalloids Infused: "C" = 0

1. Is B + C > PV? Yes No If answers to both 1 and 2 are "NO", test sample. If answer to either is "YES", obtain a pre-hemodilution sample. If no pre-hemodilution sample is available, defer donor.
 2. Is A+B+C > BV? Yes No

SIGN
 I have reviewed the above information and verify that it is complete and accurate to the best of my knowledge. The designated sample, qualified to be used for disease marker testing, has been labeled with the donor identification, date and time of collection and initiated.
CRUCETA LEE Lee Cruceta 1/27/05
 NAME (PRINT) LAST FIRST SIGNATURE DATE

AGENCY NAME		OTPO #	TEAM LEADER INITIALS
BIOMEDICAL TISSUE SERVICES		BMS-A126	LC
DONOR NAME		AGE	GENDER
LAST <u>PACE</u>	FIRST <u>JOSEPH</u>	<u>54</u>	<u>MALE</u>

BIOMEDICAL TISSUE SERVICES INFUSION SUMMARY
 Rev. 4/12/01/04 FORM F200-003

000085

Lee Cruceta certifies falsely on this document that the blood he drew from Joseph Pace is the blood that he is submitting to RTI to be screened for diseases. As a result of this fraud, two tissue banks bought Pace's tissue.

RECOVERY REPORT											
*Print all information except where signature is indicated											
Referring Hospital/Facility: <u>FUNERAL HOME</u>					Recovery Start Date: <u>1/27/05</u> Finish: <u>1/27/05</u>						
Autopsy <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No					Recovery Start Time: <u>07:55</u> Finish: <u>08:55</u>						
Cause of Death: <u>ACUTE MYOCARDIAL INFARCTION</u>					Cardiac Death Date: <u>1/26/05</u>						
Other Recovery Agency Name: _____ Organs: <u>N/A</u>					Cardiac Death Time: <u>13:30</u>						
Eyes/Cornea: <u>N/A</u> Other: <u>N/A</u>					Height: <u>5</u> ft <u>7</u> in. Weight: <u>180</u> lbs.						
RECOVERY TEAM MEMBERS											
Team Leader: (1) LAST <u>CRUCETA</u> FIRST <u>LEE</u>			2 nd Assistant: (3) LAST <u>BIFONE</u> FIRST <u>RICH</u>								
1 st Assistant: (2) LAST <u>KNAPP</u> FIRST <u>KIRSSY</u>			Trainee/Other: (4) LAST _____ FIRST _____								
TISSUES RECOVERED											
*Indicate with a 'P' for Proximal and a 'D' for Distal when not recovered as whole. When tissue is recovered for Research indicate name of research organization in the RESEARCH column											
Tissue	Research	Recovered By		Tissue	Research	Recovered By		Tissue	Research	Recovered By	
EXAMPLE		P-2	D-2	LEG ENBLOC		1	2	Femoral Vein			
Clavicle				Femur				Saphenous Vein			
Humerus		1	2	Tibia				Abdominal Aorta			
Radius				Fibula				Descending Aorta			
Ulna				Tib/Fib w/Patella				Heart for Valves			
Radius/Ulna Enbloc		1	2	Tib/Fib Enbloc				Pericardium			
Hemipelvis		1	2	Achilles w/Calcaneus		1	2	Ribs			
Iliac Crest				Skin - Back				Costal Cartilage			
Fascia Late				Skin - Lateral Thigh		1	2	Scapula			
				Skin - Lower Extremity		1	2	Spine Enbloc			
								Cancellous Bone			1
								Back Table:			3
Recovery Notes											
BLOOD & SAMPLES SENT/RECEIVED						TISSUES SENT TO					
Sample Description		# Sent		Sample Description		# Sent		List all known agencies to receive tissue			
Hospital/Coroner/ME Blood		—		Tissue Swabs		—		1. BIL LEG ENBLOC - RTI			
Recovery Blood: Tiger Tops		1		Lymph Node Vials		1		2. BIL HUMERUS, RADIUS/ULNA - RTI			
Lavender Tops		1		Brain Biopsy		—		3.			
Yellow Tops		—		Lung Biopsy		—		4. ALL OTHER TISSUES - TBA			
Blood Draw Date: <u>1/27/05</u>				Blood Draw Time: <u>07:50</u>				Blood Drawn By: <u>LEE CRUCETA</u>			
SEROLOGY TESTING											
Will your organization provide serology results? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No						What test results are you providing? (check all that apply)					
If "NO", who will be providing serology results? <u>RTI LAB</u>						<input type="checkbox"/> HIV 1/2 Ab <input type="checkbox"/> HCV Ab <input type="checkbox"/> HBsAg <input type="checkbox"/> HTLV VII Ab <input type="checkbox"/> RPR/VDR					
Will you provide HIV-PCR results? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No						<input type="checkbox"/> HIVp24 Ag <input type="checkbox"/> CMV Ab <input type="checkbox"/> HbC Ab <input type="checkbox"/> Toxoplasma <input type="checkbox"/> ABO/Rh					
I have reviewed the above information and verify that it is complete and accurate to the best of my knowledge. The donor body was reconstructed in accordance with standard protocols.											
Donor Disposition: <u>DONOR QC AND RELEASED TO FUNERAL DIRECTOR FOR TRANSPORT.</u>											
S I G N <u>CRUCETA</u> NAME (PRINT) LAST			<u>LEE</u> FIRST			<u>Lee Cruceta</u> SIGNATURE			<u>1/27/05</u> DATE		
AGENCY NAME OTPO						OTPO #					
<u>BIOMEDICAL TISSUE SERVICES</u>						<u>BM05-A126</u>					
DONOR NAME				AGE		GENDER					
LAST <u>PACE</u>		FIRST <u>JOSEPH</u>		<u>54</u>		<u>MALE</u>					
BIOMEDICAL TISSUE RECOVERY LOG				FORM F500-001							
Rev. 6/12/01/04 703249107				<u>(Bm) 101042570</u>							
						<u>000086</u>					

As team leader, Cruceta filled out recovery reports that recorded when a recovery took place, who participated, and what tissues were taken. On these reports, he routinely lied about the real time of death – in Pace’s case making it 34 hours later than it really was. The recovery of tissue took place more than 50 hours after Pace died.

DONOR INFORMATION		
<i>*Print all information except where signature is indicated.</i>		
9 / 10 / 50 DATE OF BIRTH	047-58-3783 SOCIAL SECURITY NUMBER	N/A MEDICAL RECORD NUMBER
MEANS USED FOR POSITIVE ID (Check one)		
<input type="checkbox"/> Hospital Band/ID Tag	<input type="checkbox"/> Driver's License	<input checked="" type="checkbox"/> Facility Staff <u>Gerry Garzone - Fun Director</u> (Last Name, First)
<input type="checkbox"/> Medical Examiner No.	<input type="checkbox"/> Other Source _____ (Name & Title)	
NAME OF RECOVERY STAFF VERIFYING ID: <u>LEE CRUCETA - CTBS</u>		
RACE (Check one)		
<input checked="" type="checkbox"/> White (CA)	<input type="checkbox"/> Hispanic (LA)	<input type="checkbox"/> American Indian / Alaskan Native (NA)
<input type="checkbox"/> Black (AA)	<input type="checkbox"/> Native Hawaiian/Pacific Islander	<input type="checkbox"/> Asian (AS) <input type="checkbox"/> Other
RECOVERY INFORMATION		
REFRIGERATION (Check One)	<input type="checkbox"/> Donor recovered <12 hours post cardiac asystole, documentation not required.	
	<input checked="" type="checkbox"/> Donor refrigerated within 12 hours and tissue excision began within 24 hours post cardiac asystole.	
REFRIGERATION TIME: <u>23 : 45</u>	DATE: <u>1 / 26 / 05</u>	
AUTOPSY CASE (Check one)		
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	RELEASE BY / TITLE _____	CITY _____ STATE _____ ZIP CODE _____
<input type="checkbox"/> Hospital	TELEPHONE NUMBER () _____	
<input type="checkbox"/> Medical Examiner	RESTRICTIONS _____	
<input type="checkbox"/> Other		
MOST RECENT CARE PROVIDED BY: (i.e. Hospital, Health Care Facility or Treating Physician if applicable)		
<u>N/A</u> FACILITY NAME/TREATING PHYSICIAN (IF APPLICABLE)	() - TELEPHONE NUMBER	CITY _____ STATE _____ ZIP CODE _____
<u>N/A</u> FACILITY NAME/TREATING PHYSICIAN (IF APPLICABLE)	() - TELEPHONE NUMBER	CITY _____ STATE _____ ZIP CODE _____
RECOVERY LOCATION (Check one) <u>GARZONE FUNERAL HOME</u> RECOVERY LOCATION NAME		
<input type="checkbox"/> Hospital	<input type="checkbox"/> Medical Examiner	
<input checked="" type="checkbox"/> Funeral Home	<input type="checkbox"/> Hospital Morgue	<u>PHILADELPHIA</u> <u>PA</u> <u>19135</u> CITY STATE ZIP CODE
<input type="checkbox"/> Other		
SIGN	I have reviewed the above information and verify that it is complete and accurate to the best of my knowledge. The informed consent for donation has been obtained and documented.	
	<u>CRUCETA</u> NAME (PRINT) LAST	<u>LEE</u> <u>Lee Cruceta</u> FIRST SIGNATURE DATE <u>1 / 27 / 05</u>
AGENCY NAME		OTPO #
BIOMEDICAL TISSUE SERVICES		TEAM LEADER INITIALS
DONOR NAME		AGE
LAST <u>PACE</u> FIRST <u>JOSEPH</u>		GENDER
		<u>54</u> <u>MALE</u>
BIOMEDICAL TISSUE SERVICES Rev. 3/12/01/04		DONOR DEMOGRAPHICS FORM F500-002
000088		

Cruceta records that the recovery took place at "Garzone Funeral Home" and that Gerry Garzone identified the body as Pace's. He falsely claims that the body was refrigerated.

INSTRUCTIONS

**Print all information except where signature is indicated.*

- Check here to indicate that this form is not applicable because the donor expired in a health care facility (the completion of this form is not required).

This form is required to be completed when the patient expires in a location other than a health care facility.

CIRCUMSTANCES OF DEATH

Give a brief summation of how and where the patient expired.

DONOR A NON-HOSPITAL RECOVERY. DONOR LAST SEEN AT 13:30 ON 1/26/05. NO EVIDENCE OF TRAUMA; NO MEDICAL CHART.

Is there physical evidence of intravenous interventions?

- No
- Yes, see attached infusion summary.

SOURCES OF INFORMATION

Name/Title:	<u>LINDA PACE / SPOUSE</u>	Phone No.:	<u>(25) 549- 8780</u>
Name/Title:	_____	Phone No.:	<u>() -</u>
Facility:	_____	Phone No.:	<u>() -</u>
<input checked="" type="checkbox"/> Death Certificate Attached.			
<input type="checkbox"/> Death Certificate Pending.		Requested by: _____	
		Last name	First Name
<input type="checkbox"/> Other Document: _____			

SIGN I have reviewed the above information and verify that it is complete and accurate to the best of my knowledge.

<u>CRUCETA</u>	<u>LEE</u>	<u>Lee Cruceta</u>	<u>1 127 105</u>
NAME (PRINT) LAST	FIRST	SIGNATURE	DATE

AGENCY NAME		OTPO #	TEAM LEADER INITIALS
<u>BIOMEDICAL TISSUE SERVICES</u>		<u>BM05-A126</u>	<u>LC</u>
DONOR NAME		AGE	GENDER
LAST <u>PACE</u>	FIRST <u>JOSEPH</u>	<u>54</u>	<u>MALE</u>

BIOMEDICAL TISSUE SERVICES
Rev. 3 12/01/04

CIRCUMSTANCES OF DEATH
FORM F500-005

000090

Cruceta "verifies" that Pace was last seen, with "no evidence of trauma," long after he had already died. Cruceta claims as his source the fictitious spouse, "Linda Pace."

DONOR PHYSICAL ASSESSMENT

- Manner Identified By:
 Hospital ID Band
 Driver's License
 Toe Tag
 Chain of Custody
- Describe identifying information from band, tag or chain of custody:
FLORAL DIRECTOR - VISUAL IDENTIFICATION WITH
REVEREND TX PACE'S DISPOSITION WITH
FLORAL DIRECTOR
- (Key to Schematics)
 (8) IV/Arial Line
 (9) Team Blood Draw Site
 (10) Laceration/Wound
 (11) ID Band/Tag
 (12) Needle Entry Site
 (13) Organ Recovery Incision
 (14) Body Piercing (Describe)
 (15) Rash
 (16) Scar (Surgical/Trauma)
 (17) Tattoo - (Describe)
 (18) Urethral Catheter
 (19) Skin Lesion
 (20)
 (21)

Personnel Confirming Donor Identification:
LEE CRUCETA Date/Time: 1/27/05 / 07:45

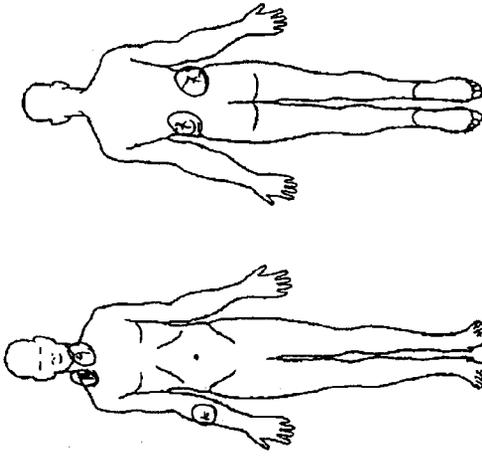
Recovery Team Assessment

- Is there evidence of:
 Unexplained jaundice/icterus Yes No
 Physical evidence for risk of sexually transmitted diseases Yes No
 Enlarged lymph nodes Yes No
 Anal tears/perianal warts Yes No
 Oral thrush Yes No Unable to visualize
 Non-medical injection sites Yes No
 Infectious precautions known Yes No
 Trauma/infection to retrieval sites Yes No
 Blue/purple spots/lesions consistent with Kaposi's sarcoma Yes No

Explain if unable to visualize oral cavity, or if any answers are "Yes"
N/A

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Donor Physical Assessment Completed By: LEE CRUCETA Date: 1/27/05



AGENCY NAME		OTPO #		TEAM LEADER INITIALS	
BIOMEDICAL TISSUE SERVICES		0M05-A126		LC	
DONOR NAME		AGE		GENDER	
LAST PACE		54		MALE	

BIOMEDICAL TISSUE SERVICES
 Rev. 2/12/01/04
 DONOR PHYSICAL ASSESSMENT FORM
 FORM F500-012

On this form, Cruceta purports to record a visual physical assessment of Pace's body. On these forms, Cruceta invariably marked the "no" box for any condition that might make a body unsuitable for harvesting.

CROSS-CONTAMINATION CHECKLIST

Please indicate below whether the following items have been addressed prior to recovery:

- | | | |
|--|---|-----------------------------|
| 1. Donor identification verified as per SOP 200-080 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Supplies assembled as per SOP 300-020 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Sterilization & decontamination of instruments as per SOP 300-030 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Recovery preparation in a non-standard setting as per SOP 300-050 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. Opened sterile trays & packaging as per SOP 300-060 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 6. Surgical hand scrub as per SOP 300-070 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 7. Gowning & gloving as per SOP 300-080 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 8. Positioned & prepared the donor as per SOP 300-090 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |

SIGN I have reviewed the above information and verify that it is complete and accurate to the best of my knowledge.

<u>CRUCETA</u> NAME (PRINT) LAST	<u>LEE</u> FIRST	<u>Lee Cruceta</u> SIGNATURE	<u>1/27/05</u> DATE
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AGENCY NAME	OTPO #	TEAM LEADER INITIALS
BIOMEDICAL TISSUE SERVICES	0M05-A126	LC
DONOR NAME	AGE	GENDER
LAST <u>PACE</u> FIRST <u>JOSEPH</u>	<u>54</u>	<u>MALE</u>

BIOMEDICAL TISSUE SERVICES
Rev. 2 12/01/04

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CROSS-CONTAMINATION CHECKLIST
FORM F600-018

On this form Cruceta claims to have verified procedures for identifying the body, sterilizing equipment, preparing the room, scrubbing and dressing. Another cutter, however, said that these procedures were not followed.

NONSTANDARD TISSUE RECOVERY SITE ASSESSMENT

Check the appropriate box below indicating where the tissue recovery is taking place:

- Funeral Home Morgue Open Autopsy Suite
 Other - Explain: _____

The above marked site is inspected for the following parameters (check "Yes" or "No" for each item):

Prior To Recovery:

- | | | |
|--|---|-----------------------------|
| 1. Does the tissue recovery site have adequate floor and tabletop space for separation of sterile instrumentation and aseptic recovery processes? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Does the tissue recovery site have adequate lighting to perform physical assessment and tissue recovery? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Does the tissue recovery site have adequate plumbing and drainage for tissue recovery? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Does the tissue recovery site ensure a maintained and controlled, closed airflow system so that there is no direct access to the outside of the building? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. Is the tissue recovery site free from insects, rodents and other pests? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 6. Does the tissue recovery site have access to a hand-washing area to perform an adequate hand/arm surgical scrub? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 7. Is the tissue recovery site free from aerosols or other sources of potential air borne contamination? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 8. Has the tissue recovery site been properly prepared by cleaning and disinfecting all working surfaces and, as needed, isolation draping is placed over room furniture, hung on nearby walls, and/or over open drains to reduce the bioburden? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |

If any of the above parameters have not been satisfied (i.e. "No" answers), the recovery site is **NOT** suitable for tissue recovery.

During Recovery:

- | | | |
|--|---|-----------------------------|
| 1. As Team Leader, have you restricted human traffic and ensured that all personnel entering the recovery area are properly outfitted and their movement controlled? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. As Team Leader, have you ensured that no other activities (i.e. embalming, autopsy) have occurred simultaneously in the same room or area as the tissue recovery? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |

Post Recovery:

- | | | |
|---|---|-----------------------------|
| 1. Has post recovery cleaning of the tissue recovery site occurred? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Have all contaminated/biohazardous supplies been properly disposed of or adequately contained and transported to disposal site after recovery? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |

S I have reviewed the above information and verify that it is complete and accurate to the best of
I my knowledge
G CRUCETA LEE Lee Cruceta 1/27/05
N NAME (PRINT) LAST FIRST SIGNATURE DATE

AGENCY NAME		OTPO #	TEAM LEADER INITIALS
BIOMEDICAL TISSUE SERVICES		BMO5-A126	LC
DONOR NAME		AGE	GENDER
LAST	FIRST	AGE	GENDER
PACE	JOSEPH	54	MALE

BIOMEDICAL TISSUE SERVICES
Rev. 1/12/01/04

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NONSTANDARD TISSUE RECOVERY SITE ASSESSMENT
FORM F300-001

Auditors relied on this type of self-reporting, rather than inspection, to determine the appropriateness of the Garzones' embalming room for recovery. A spot check would have revealed unsanitary conditions, improper ventilation, and no refrigeration facilities.

