Legal Basis of Global Tissue Banking

A Proactive Clinical Perspective

Editor

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A RETROSPECTIVE LOOK AT THE LARGEST RECALL OF PROCESSED BONE TISSUE IN HISTORY

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> Human corpses "sat in an alley, unrefrigerated for days, and, after tissue was removed, all that would remain was a head and bloody torso."
>
> *Com. v. Mastromarino*, 2 A.3d 581, 588 (Pa. Super. Ct. 2010)

INTRODUCTION

Beginning on September 30, 2005, a series of announcements was made by bone tissue processors concerning discrepancies in donor documentation provided by Biomedical Tissue Services Ltd (BTS). Through October 14, 2005, the processors each announced a voluntary market withdrawal and/or recall of allograft derived from BTS donors. The Food and Drug Administration (FDA), on October 26, 2005, released an announcement that included concerns that BTS may not have adequately screened donors for infectious disease. The FDA ordered BTS operations to be shut down. BTS had supplied tissue for several years to at least five companies that processed the tissue into allografts, including Regeneration Technologies, Inc., Tutogen, LifeCell Corporation, Central Texas Regional Blood and Tissue Center, and Lost Mountain Tissue Bank, Inc. All of the bone tissue processed into allografts from tissue recovered by BTS were the subject of an October 2005 FDA supervised recall. The FDA and Centers for Disease Control and Prevention (CDC) recommended that implanting

physicians offer to provide patients access to testing for the diseases for which donors were generally screened and report any positive test results to the processors and/or the FDA directly. From June 2002 through October 2005, approximately 25,000 BTS-recovered tissue products were distributed to all 50 states and internationally.

In May 2006, the CDC in its morbidity and mortality weekly report discussed its investigation into the BTS recalled tissue. In that report the CDC repeated its recommendation that allograft recipients be tested for hepatitis B (HBV), hepatitis C (HCV), human immunodeficiency virus (HIV), and syphilis. Plaintiffs in the United States who underwent surgery in which one or more allografts from BTS were implanted initiated lawsuits against funeral homes, recovery agencies, processors, and a distributor. The first lawsuit was filed on November 18, 2005, and as of October 2007 there were over 700 plaintiffs suing in US state and federal courts, that total eventually reaching 1,000 claims.

The principals of BTS were indicted for crimes related to the unauthorized recovery of tissue and falsification of donor screening records. Prison sentences were issued to numerous parties involved, both for unauthorized recovery and for failure to meet the aseptic processes dictated by best practices.

After litigation commenced, the cases were consolidated and assigned to one federal judge for pre-trial proceedings on June 21, 2006. The defendants jointly filed a motion for summary judgment on October 16, 2007. On September 4, 2008, oral argument was conducted before the Federal Court, and thereafter on October 22, 2008, the Federal Judge issued a 105-page opinion in which he concluded that the bone tissue implanted was not capable of transmitting HBV, HCV, HIV, syphilis, or cancer.

Fortunately, to this day there has been no report of disease transmission by bone tissue recovered by BTS and distributed by any of the processors. The failure by the CDC and the FDA to announce any case of disease transmission, now, nine years later, adds to the weight of the scientific conclusion that disease transmission could not occur.

THE CRIMINAL SCHEME THAT INITIATED THE RECALL

At the beginning of the twenty-first century, the demand for human tissue far surpassed available supply; a man named Michael Mastromarino

decided to capitalize on this shortage. In 2002, Mastromarino created a corporation called Biomedical Tissue Services (BTS), through which he recovered human tissue from cadavers and supplied them to tissue banks around the United States. Upon founding BTS, Mastromarino, a former dentist whose license was suspended due to drug abuse, became licensed as a recovery agency for human tissue and began seeking out funeral homes to provide him with access to cadavers.

Mastromarino originally worked with a few funeral homes in New York and New Jersey. These homes provided him with access to cadavers from which he and his team of "cutters" could harvest tissue without the consent of the deceased or their next-of-kin. Mastromarino reportedly paid undertakers up to $1,000[1] per corpse.

Mastromarino and his team reconstructed the cadavers with PVC pipe to conceal the unapproved removal of tissue. Thereafter he sought a simpler process to further his criminal enterprise. An arrangement with a funeral director who had access to a crematorium would provide him with cadavers that would not need to be reconstructed after harvesting of the tissue was complete. Mastromarino met with the co-owners of Liberty Crematory to foster this arrangement, which led to a significant increase in his recovery of bone tissue.

In February 2004, Mastromarino began working with James McCafferty, Louis Garzone, and Gerald Garzone. Each operated separate funeral homes and were partners in a crematorium business, Liberty Cremation, Inc., in Philadelphia, Pennsylvania. Together, Mastromarino, the Garzones, and McCafferty, worked to illegally enrich themselves by trafficking in stolen body parts. Without obtaining the families' consent, they procured bones, skin, tendons, spines, and other tissue from the dead entrusted to the care of Philadelphia funeral homes for cremation and burial.

The harvested tissue was taken from corpses with flagrant disregard for regulations and procedures designed to ensure the safety of body parts. Safe tissue protocols require tissue removal within 15 hours of death. The bodies Mastromarino and his team harvested tissue from routinely sat for days without refrigeration, sometimes in an alley or a garage. One corpse reportedly sat for 113 hours after death, another for 100 hours.

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[1] All monetary references are in US dollars.

The cutters used power tools to remove spines and bones from the bodies. Without the need to prepare the body for a viewing, Mastromarino and his team went "whole hog" on the bodies to be cremated. The process of harvesting tissue by regulatory standards would take several hours, yet Mastromarino and his "cutters" tore bodies apart in 30 minutes taking everything they could.

The lack of respect for the deceased, illegality of harvesting, and deliberate neglect of regulatory law were not the end of the scheme. In order to sell the tissue they harvested, Mastromarino and his associate, Lee Cruceta, falsified records and forged documents. Mastromarino and Cruceta falsified facts including name, time of death, and health condition of the cadavers. Mastromarino deliberately replaced blood samples from bodies that might have been infected with HIV and HCV, evading tests designed to screen for these diseases, and fabricated medical histories for individuals who died from cancer or septic diseases.

Mastromarino and his team took the harvested tissue from the diseased and decaying bodies, and sold it to companies that then distributed bone tissue to hospitals worldwide for use in medical procedures. BTS supplied tissue for several years to at least five companies that processed the tissue into allografts. Overall, the total amount tissue processing companies paid to BTS for tissue stolen in all of the funeral homes was approximately $5,000,000.

Several 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 Philadelphia funeral homes. At least five Philadelphia-area and 41 Pennsylvania hospitals implanted BTS tissue in patients.

New York Detective Patricia O'Brien sparked the investigation that uncovered the scheme when she investigated a Brooklyn funeral home for stolen funds in the fall of 2004. When she visited the home, she noticed a room that looked like an operating room. She looked into the home's files and discovered that the previous owner had been running more than a funeral business.

Mastromarino, Cruceta, and the funeral directors had conducted their operation for three-and-a-half years under the noses of federal and

state regulators and private auditors before they were caught. The Philadelphia grand jury report concluded that the crimes "went undetected because current regulations and overseers failed to take into account the enormous incentives and opportunities to commit theft and fraud in the body tissue industry." (In re County Investigating Grand Jury XXI, 2007).

After the ghoulish scheme was uncovered, BTS records showed that they had procured tissue from a total of 1,077 bodies in three states: Pennsylvania, New Jersey, and New York.

In 2006, the case was submitted for review to the Grand Jury. The Grand Jury Report recommended that officials prosecute Mastromarino and his accomplices to the fullest extent possible. Mastromarino pled guilty to 1,353 separate counts including corrupt organization, conspiracy, theft by unlawful taking, deceptive business practices, and abuse of corpse. He was sentenced on October 22, 2008 to an aggregate of 25 to 58 years in prison.

Louis and Gerald Garzone were each sentenced to eight to 20 years in prison for illegally selling body parts for use in surgeries. Lee Cruceta was also sentenced to eight to 20 years for his part in the criminal scheme. James McCafferty was sentenced to three-and-a-half to ten years.

In an ironic twist of fate, Michael Mastromarino died in July 2013, while serving out his prison sentence, from complications, including bone cancer.

FEDERAL AND LEGAL INTERVENTION

Nearly a year after Detective O'Brien's suspicions sparked the investigation into Mastromarino's scheme, the FDA and CDC became involved. On September 29, 2005, a tissue-processing company discovered inaccuracies in donor records and notified the FDA. This launched an FDA investigation into BTS, which determined that tissues recovered from BTS might not have met donor eligibility requirements and were not properly screened for certain infectious diseases.

The FDA Current Good Tissue Practice rules require manufacturers to recover, process, store, label, package, and distribute human tissue

products to prevent introduction, transmission, or spread of communicable diseases. FDA regulations require that each donor be screened and tested prior to accepting their tissue. Donors are screened through a review of their medical records, a physical assessment, and questioning of their next-of-kin to determine whether clinical evidence of relevant communicable diseases exists. Blood samples from each donor must be provided to the testing laboratory for donor testing of HIV, hepatitis B, hepatitis C, and syphilis before tissues are released for distribution.

The FDA investigation determined that information regarding cause of death for some BTS donors was not consistent with death certificate data obtained from the states where the deaths occurred. The FDA also determined that BTS had failed to control conditions adequately during tissue recovery and did not recover tissues in a manner that would prevent contamination.

BTS supplied tissue over several years to at least five companies that processed the tissue into allografts. Most of these tissue allografts were bone or demineralized bone matrix; others included skin and soft tissue. The tissues were sent to processors, who distributed them through one or more sub-distributors or directly to clinicians and healthcare facilities. Before distribution, tissues were disinfected by tissue processors to reduce or eliminate contamination with bacteria, fungi, or viruses. Over 10,000 allografts of recovered BTS tissue were implanted.

In October 2005, the FDA supervised a recall of all tissue recovered by BTS. The five processing companies that received BTS-recovered tissue products, Regeneration Technologies, Inc., Tutogen, LifeCell Corporation, Central Texas Regional Blood and Tissue Center, and Lost Mountain Tissue Bank, Inc., voluntarily recalled all tissue. The processing companies sent letters to healthcare facilities notifying them of the recall and recommending they provide access to testing for transplant recipients.

About two weeks later, the FDA notified the public through an announcement providing information about its investigation into human tissue recovered by BTS (FDA News Release, 2005). The release stated that the FDA and CDC believed the risks of contracting infectious disease from these tissues were low because the tissues were routinely processed using methods that reduce the risk of infectious disease, and that no

adverse reactions related to these tissues had been reported to the FDA at that time. The release, however, recommended "implanting physicians inform their patients that they may have received tissue from a donor for whom an adequate donor eligibility determination was not performed." (FDA News Release, 2005). The release further noted that while the overall risk of infection was likely low, patients should be provided access to testing for the relevant communicable diseases: HBV, HCV, HIV, and syphilis.

The first civil lawsuit brought by an allograft recipient was filed in New Jersey Superior Court, Middlesex County, on November 18, 2005, and the case was removed to a federal court. After that, over 700 plaintiffs filed lawsuits in federal and state courts against funeral homes, recovery agencies, processors, and a distributor. Plaintiffs were patients who received allograft implants. On June 21, 2006, the Judicial Panel on Multidistrict Litigation consolidated the cases filed in federal court as *In re Human Tissue Products Liability Litigation* in the United States District Court for the District of New Jersey.

In March 2006, the FDA issued an update to its October 2005 press release (FDA News Release, 2006). This update reported that the FDA had additional information and confirmed that blood samples did not come from the same donor as the linked tissues in some instances. The FDA and CDC again recommended that physicians offer patients access to testing for HBV, HCV, HIV, and syphilis. The update also noted that patients should report any adverse reaction possibly related to a tissue transplant to their tissue processing firm.

In its May 26, 2006, Morbidity and Mortality Weekly Report, the CDC reported on its investigation with the FDA into the BTS recall (CDC MMWR, 2006). In the report, the CDC recommended testing for patients who had their allografts implanted more than six months previously. The CDC advised that patients who tested negative for disease after implants in place for six months did not need further testing.

On October 20, 2006, defendants in the consolidated federal litigation, processors and distributors of allografts, Medtronic, Inc., Medtronic Sofamor Danel USA, Inc., SpinalGraft Technologies, LLC, and Regeneration Technologies, Inc., filed a motion to dismiss plaintiffs' complaints for failure to state a claim. Defendants argued that even if

BTS failed to properly screen donors to minimize the risk of disease transmission, no virus could survive the sterilization process and storage at room temperature for a prolonged period of time.

The Court held oral arguments on March 28, 2007. At that time, the Court reserved on the motion to dismiss and converted it into a summary judgment motion on the issue of causation. The same defendants jointly filed a motion for summary judgment on October 16, 2007 on the issue of general causation for the various tort claims asserted by the recipient plaintiffs.

The motion centered on questions of science previously posed by the court. The court asked the parties to assume that the bone tissue from the cadavers was infected with HCV, HIV, syphilis, cancer, and prions, and had not undergone any processing. The court then posed two questions: (1) Can this bone tissue still transmit one of these diseases to a donee?; (2) What is the incubation period for these diseases? These questions had been suggested by the defendants, since it allowed the court to bypass any need to assess the merits of the complicated sterilization processes. Consequently, the sterilization procedures would be additional steps in ensuring that the bone allografts do not infect recipients with infectious diseases.

At oral argument, the defendants argued that the admissible evidence in this case established that there was no risk of disease transmission. In answering the first question posed by the court, the defendants maintained that lyophilized bone tissue stored at room temperature for 30 days or more cannot transmit HBV, HCV, HIV, syphilis, or cancer. The defendants further argued that the incubation period for each of the diseases in question is six months or less, and all of the plaintiffs received their allograft implants more than six months ago.

Ultimately, in a 105-page opinion, Federal Judge Martini granted summary judgment for the defendants excluding some of plaintiffs' expert testimony and ruling in favor of the defendants' arguments on the two proposed questions.

DISEASE TRANSFERS BY BONE

Judge Martini was able to rule in favor of the defendants' motion for summary judgment in the BTS litigation based on their expert testimony and related literature review. Through their memorandum of law and oral

argument, the defense presented a reliable scientific history of the capability of disease transfers by lyophilized bone tissue. The plaintiffs failed to present reliable scientific and medical evidence to counter these arguments. Rather, they only offered subjective belief and unsupported speculation.

Over the past 65 years bone tissue allografts have resulted in 17 cases of viral disease transmission, two cases of bacterial disease transmission, and one case of transmission of cancer.

Bone Tissue Transmitting Viral Disease

Lyophilized bone tissue has been in use since 1951. There are no known cases of HIV or disease transmission through lyophilized bone. Only frozen bone tissue allografts, not lyophilized bone tissue allografts, have caused infection. There have been 17 cases of viral disease transmission.

Shutkin reported the first case of the transmission of viral disease by frozen bone in 1954 (Shutkin, 1954). This case concerned a medical student who became infected with HBV transmitted from donor bone. Subsequently there have been nine reported cases of HIV transmission and 7 cases of HCV transmission, all of which resulted from implantation of frozen bone allografts. (Table 13.1 details the reported cases of recipients infected with HIV, HCV, or HBV.)

Freezing preserves the infectivity of enveloped viruses, presumably by keeping their lipid membranes intact for years (Salvucci, 2011). In order for viruses to replicate, a fusion event must occur between the virus's lipid envelope and the cell's lipid membrane. This fusion event results in the building of a bridge enabling the viral DNA or viral RNA to enter the cell (Tscherne *et al.*, 2006). Water is an integral part of the maintenance of the virus's lipid envelope. Lacking water, the lipid membrane will collapse from a lamellar bilayer shell into hexagonal arrays and sheets (Bode and Read, 2000).

When moisture is removed from the bone through drying or lyophilization, the enveloped viruses are inactivated by destroying the lipid envelope. Several studies have shown that viral infectivity rapidly dissipates following drying and storage at room temperature. Laboratory studies have shown that HIV survives when dried at room temperature for at most seven days (Sattar and Springthorpe, 1991), and HBV, dried

Table 13.1. Reported cases of recipients infected with HIV, HCV, and HBV.

Year disease transmitted	Year reported	Allograft	Processed/Unprocessed	Number and disease	Reference
1954	1954	Cancellous bone probably from femoral head	Frozen/Unprocessed	1 HBV	Shutkin
1984	1988	Frozen/femoral head	Unprocessed	1 HIV	CDC-MMWR
1984–1985	1996	Bone	Frozen/Unprocessed	4 HIV	Schratt
1985	1991 and 1992	2 femoral heads and 1 tendon with bone	Frozen/Unprocessed	3 HIV	Simonds
1990	1992	Femoral head	Frozen/Unprocessed	1 HCV	Eggen
1990	1995	1 patellar tendon and 1 femoral head	Tendon in bacitracin and polymyxin and frozen; and femoral head was placed directly in freezer	2 HCV	Conrad
1996	2001	Femoral head	Unspecified, but assumed frozen based upon placement into hospital bone bank; also unprocessed	1 HIV	Chien-Min Li
1998	2003	Cancellous bone chips	Soaked in antibiotic, alcohol, and frozen	1 HCV	Trotter
2000	2005	Three tendons with bone	Lavaged with sterile water, then soaked in isopropyl alcohol, antibiotics, and fresh frozen	3 HCV	Tugwell

on a stainless steel surface, can survive for a period of up to 14 days (Sattar and Springthorpe, 1996).

In a 2007 study, chimpanzees were injected with three HCV infectious aliquots, which were previously air dried at room temperature for 16 hours, four days, and seven days (Kamili *et al.*, 2007). The Kamili study reported that the aliquot dried for 16 hours transmitted HVC, while the aliquot dried for four days did not.

Studies specifically dealing with lyophilization have shown that enveloped viruses survive lyophilization, yet they establish a rapid loss of infectivity on storage. In a 2005 study, the enveloped virus, vesicular stomatitis virus (VSV), was tested following lyophilization and a three-to-four-hour log reduction was noted (Uhlenhaut *et al.*, 2005). The time elapsed between lyophilization and testing of VSV was less than one hour. In a similar study, feline leukemia virus (FeLV) was determined to survive lyophilization, but for a period of less than seven days (Crawford *et al.*, 2004).

The life of the lipid envelope can be extended if it is protected by freezing, or by adding cryopreservative agents prior to drying (Salvucci, 2011). Drying without cryopreservative agents accelerates the progression toward inactivity. Air-drying and lyophilization do not inactivate enveloped viruses; however, the process of water removal using either method limits infectivity of the viruses to a certain period of time. Consequently, the evidence leads to the conclusion that bone, lyophilized and stored at room temperature for 15 days or more, is not capable of transmitting HIV, HBV, and HCV.

Bone Tissue Transmitting Bacterial Disease

Disease transmission resulting in bacterial infection would be known immediately following implantation of tissue. Although there have been two instances of bacterial disease transmitted by allografts (summarized in Table 13.2), there were no claims for bacterial disease involved in the BTS litigation.

Bone Tissue Transmitting Cancer

There is only one reported case of cancer transmitted by frozen bone allografts (see Table 13.3).

Table 13.2. Reported cases of recipients infected with bacterial disease.

Year disease transmitted	Year reported	Allograft	Processed/ Unprocessed	Number and disease	Reference
1953		Ribs	Frozen and solution containing penicillin and streptomycin	1 tuberculosis	James
2001	2001	Knee osteo-chondral (bone-cartilage)	Processed	1 clostridium	CDC-MMWR

Table 13.3. Reported case of recipient infected with cancer.

Year disease transmitted	Year reported	Allograft	Processed/ Unprocessed	Number and disease	Reference
1991	1997	Femoral head	Fresh frozen unprocessed	1 HTLV-1	Sanzen

TRANSMISSION OF VIRAL DISEASE IN BTS LITIGATION

None of the represented plaintiffs in the BTS litigation received frozen bone tissue allografts. Based on the plaintiffs that provided tissue identification information, the defendants determined that the implanted allografts had been lyophilized and stored at room temperature for a period of over 30 days in all but one instance. In the outlying instance, the allograft was stored for 22 days at room temperature and that plaintiff tested negative for infectious disease ten months after implantation surgery.

All parties agreed that frozen bone allografts could transmit disease. Additionally, all parties agreed that unprocessed bone tissue stored at room temperature could transmit HIV, HBV, HCV, syphilis, and cancer for an initial window of time. The court focused its inquiry at oral argument on the period of time lyophilized bone tissue allografts stored at room temperature can transmit disease; and, the incubation period for detection.

In answering the two questions posed by the court, the defendants maintained that bone tissue stored at room temperature for 30 days or more cannot transmit HBV, HCV, HIV, syphilis, or cancer. The defendants

further argued that the incubation period for each of the diseases in question is six months or less, and all of the represented plaintiffs received their allograft implants more than six months previously. Plaintiffs argued for no specific period of time in which transmission can occur, but that it is longer than 30 days. Plaintiffs further argued that the detection of HBV and HCV infection could take up to two years and HIV infection between six and eight months.

Plaintiffs and defendants each presented expert opinions on the time period of infectivity for bone tissue stored at room temperature. Experts on both sides agreed that viruses lose infectivity over time when kept at room temperature. Plaintiffs' experts, Dr Busch, a blood specialist, and Dr Kowalski, a microbiologist, acknowledged that enveloped viruses, like HBV, HCV, and HIV, lose infectivity at room temperature over time. Plaintiffs' expert Dr Busch testified that he did not recall "in those experimental studies a time period beyond 14 days referenced with respect to residual infectivity" (In re Human Tissue Products Liab. Litig., 2008).

Plaintiffs' expert Dr Parisian was unable to explain why the studies she relied on supported her conclusion regarding the ability of bone allografts to transmit disease beyond 30 days. She further based her determination that there is always a risk of disease transmission without donor screening because of the CDC's reliance upon both donor screening and processing to ensure the safety of bone allografts. The court found her opinions, at best, nothing more than pure speculation.

The court additionally found that Dr Kowalski's opinions suffered from the same issues as Dr Parisian's opinions in that he failed to articulate the scientific and medical rationale for extrapolating the results of the available studies to the set of facts in the litigation.

Defendants presented studies by Van Bueren and Resnick, which showed substantial reductions of HIV titer over 30 days or less, even with the use of stabilizers to protect the virus. Defendants' experts on HIV, Drs Kuritzkes, Richman, Rutala, Kainer, and Jarvis, all agreed that bone tissue kept at room temperature for 30 days or more cannot transmit HIV.

Neither plaintiffs' nor defendants' experts opined that syphilis can be transmitted by unprocessed bone tissue. Syphilis is a bacterial disease and

can survive only briefly in the environment outside of blood. In whole blood at temperatures much lower than room temperature, syphilis loses infectivity in, at most, five days. Similarly, plaintiffs failed to provide any argument to suggest bone tissue can transmit cancer after 30 days or more. Plaintiffs additionally failed to provide more than speculative opinions regarding the risk of transmitting prion disease.

After an in-depth review of plaintiffs' expert opinions, Judge Martini concluded that plaintiffs failed to establish credible expert testimony to conclude that lyophilized bone tissue stored at room temperature could transmit any of the named diseases after 30 days.

The court next addressed the issue of incubation. The standard adopted by the CDC and FDA is that the incubation period for HBV, HCV, and HIV is less than six months.

Without providing any scientific or medical articles to support his opinions, plaintiffs' expert Dr Manzarbeitia offered three different opinions with respect to the incubation period for HCV, including "up to twelve months," "six weeks to ten years" and "six weeks and eighteen months to two years with appropriate testing" (In re Human Tissue Products Liab. Litig., 2008). Plaintiffs' expert Dr Klein opined that the incubation period for HBV and HCV was "two years or greater" from the time when a person has been exposed to when that person will test positive (In re Human Tissue Products Liab. Litig., 2008). Dr Klein based his opinion upon his clinical experience in hepatology and studies by Beld, Prieto, and Dickson, which all concluded that the period from infection to detection via antibody testing for HBV in the liver transplant population and HCV among injecting drug users was extended to over two years.

Plaintiffs' experts Manzarbeitia and Klein relied heavily on extrapolating experience with liver transplants. The court found the extrapolation of experience with organ transplants to bone allograft transplants unreliable, as each expert failed to provide any basis for his extrapolation. Indeed, it would be hard to equate the transplanting of live blood filled organs with the transplanting of lyophilized bone stored at room temperature in excess of 30 days.

Defendants moved to exclude the proposed testimonies of Drs Parisian, Kowalski, Klein, and Manzarbeitia regarding the transmission of HBV, HCV, HIV, syphilis, cancer, and prion disease, and the

proposed testimonies of Drs Klein and Manzarbeitia regarding the length of the incubation period for failure to meet the standards for the admission of expert evidence.

Judge Martini ruled to exclude the testimony of plaintiffs' experts, noting that "plaintiffs have failed to provide any reliable evidence to support their claims of general causation with respect to the transmission of HIV, HBV, HCV, cancer, and syphilis through unprocessed (lyophilized) human bone tissue that has been stored at room temperature for thirty days or more before transplantation into an individual and the transmission of prion disease through human cadaveric bone tissue." (In re Human Tissue Products Liab. Litig., 2008).

Judge Martini further held that "[w]ith the Court's exclusion of certain opinions of plaintiffs' experts, . . . the Court is left with no evidence in support of plaintiffs' claim of general causation" (In re Human Tissue Products Liab. Litig., 2008). Thus, Judge Martini granted summary judgment in favor of defendants based on the following: "(1) Unprocessed bone tissue and bone paste stored at room temperature for thirty (30) days or more is not capable of transmitting HBV, HCV, HIV, syphilis, or cancer; (2) Unprocessed bone tissue and bone paste is not capable of transmitting prion disease; (3) Federal plaintiffs who have tested negative for HBV, HCV, HIV, and syphilis more than six (6) months after their bone tissue or bone paste transplant surgery cannot establish general causation with respect to HBV, HCV, HIV, and syphilis." (In re Human Tissue Products Liab. Litig., 2008).

CONCLUSIONS

The BTS litigation highlights the importance of each tier in a system to properly cover for all risks. The tissue processing companies in this case were victimized by BTS's blatant disregard for safe tissue practices. Nevertheless, their sterilization methods, along with lyophilization and storing at room temperature for a period longer than 30 days prior to implantation, protected the public. Fortunately, disease has not been transmitted by BTS bone tissue. Indeed, to this day, neither the FDA nor the CDC has announced even a single case of disease transmission related to the recall of BTS tissue.

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