

Lutheran Hospital of Indiana. (Complaint, ¶12). This surgical procedure involved the insertion of bone and/or bone marrow from another human being, also referred to as an allograft. (Complaint, ¶14). Plaintiff alleges that Defendant Biomedical Tissue Services (hereinafter BTS) obtained the graft tissue from a cadaver at one of a number of different funeral homes. (Complaint, ¶15). It is Plaintiff's theory that Garzone Defendants and Dr. Michael Mastromarino arranged for the illegal removal and distribution of graft tissue from Garzone Funeral Homes. (Complaint, ¶16). Biomedical Tissue Services then obtained the graft tissue from the Louis Garzone Funeral Home, while Defendants Medtronic and RTI supplied the allograft material and supplied the human tissue that was used in Plaintiff's surgery at Lutheran Hospital of Indiana. (Complaint, ¶15-17).

MSD and RTI state that they are registered with and regulated by the Food and Drug Administration of Tissue Banks and are licensed as Tissue Banks by the states of California, Florida, Maryland and New Jersey. (MSD's Memorandum of Law In Support of Defendant's Motion to Determine Preliminary Objections, pg. 2). RTI uses a validated sterilization process on human bones prior to its distribution as an allograft. *Id.* As of March 2003, the Center for Disease Control (CDC) was aware of only sixty-two (62) cases of allograft-associated infection from 3.7 million implants, and none of the cases derived from processed bone which was used in Plaintiff's case. *Id.* at 3.

Plaintiff has since undergone a litany of blood tests, however all of the tests have come back negative for any communicable and infectious diseases.

Plaintiff commenced this cause of action on April 26, 2006, alleging various claims of negligence, strict liability and breach of warranty against Garzone defendants, Biomedical Tissue Services, Ltd., Dr. Michael Mastromarino, Medtronics and RTI.

Specifically, Plaintiff alleges in its counts of negligence and strict liability claims that Defendants were negligent in removing, distributing, supplying and inserting an allograft that could have contained infectious and communicable diseases, without previously screening the graft and its donors. (See Complaint, ¶¶23-89). Plaintiff's breach of warranty claims assert that the allograft did not adequately or accurately warn her of the dangers of infections and was not safe for its intended use. (Complaint, ¶¶94-106).

On June 16, 2006 RTI filed Preliminary Objections to Plaintiff's Complaint. Medtronics thereafter filed their Preliminary Objections on June 21, 2006 and Garzone filed their Preliminary Objections on July 7, 2006. Plaintiff responded to these Preliminary Objections accordingly. By Orders dated October 5, 2006, the trial Court granted Defendants Preliminary Objections and dismissed all claims against them. Plaintiff thereafter attempted to appeal these Orders to the Superior Court, but then discontinued the action due to the fact that the Orders of October 5, 2006 were not final Orders pursuant to Pa.R.A.P. 341. (See Order of Superior Court dated 12-15-06, 2926 EDA 2006).

On June 8, 2007, Plaintiff filed a Motion to Enter Default Judgment and requested an Assessment of Damages hearing for the remaining defendants Biomedical and Dr. Mastromarino. (See Docket). The Motion was assigned to Judge Sandra Moss. (See Docket). By Order dated July 13, 2007, Judge Moss entered default judgment against Dr. Mastromarino and Biomedical and assessed damages of zero (\$0.00) dollars because Plaintiff had failed to prove that she sustained any cognizable injury.

On August 2, 2007, Plaintiff filed her Notice of Appeal from the Judgment of July 13, 2007 and issued their Statement of Matters accordingly.

The issue on Appeal is whether the trial Court committed an error of law and/or abused its discretion in granting Defendants' Preliminary Objections where Plaintiff failed to plead a cognizable injury as required under the law.

LEGAL ANALYSIS

A. NEGLIGENCE CLAIMS

Plaintiff's Complaint asserts that Garzone, LTI and Medtronics were negligent in removing, distributing, supplying and inserting the allograft and they should be held liable under the circumstances. Plaintiff contends that because she may have been exposed to a potential infectious or communicable disease it increased the risk of her contracting an illness thereby causing her trepidation. (Complaint, ¶19-22). However, Plaintiff's Complaint did not and Plaintiff cannot allege actual exposure to infectious diseases and therefore her negligence claims based on her fear of contracting a disease was properly dismissed.

To recover for "fear of disease" in Pennsylvania, an asymptomatic plaintiff must allege actual exposure to the disease in question. *Shumosky v. Lutheran Welfare Servs. of Northeastern Pa.*, 2001 PA Super 285, 784 A.2d 196, 201 (2001). In *Shumosky*, our Superior Court defined actual exposure as consisting of two elements: (1) a scientifically accepted method of transmission of disease and (2) the presence of a positive specimen. *Id.* At 201. In applying this rule, our Federal Courts, in expressly interpreting and applying Pennsylvania law, found no actual exposure where a plaintiff could not show that a needle that struck him was ever used on an AIDS patient. *Burk v. Sage Products, Inc.*, 747 F. Supp. 285, 287 (E.D.Pa. 1990). Plaintiff in this case has not alleged the allograft she received came from an individual that had any infections. Nor can actual

exposure be inferred from the allegations of the Complaint. Pennsylvania case law supports the position that plaintiff must show exposure to the agent which has the potential to cause the disease. *Id.* At 287. (citing *Cathcart v. Keene Industrial Insulation*, 324 Pa. Super. 123, 471 A.2d 493 (1984)). In *Burk*, the Court found no actual exposure where an asymptomatic plaintiff had been stuck with a needle on a hospital floor allegedly populated by AIDS patients. *Id.* The *Burk* Court found where a plaintiff tested negative, *more than a good chance of infection was required to establish a cause of action.* (emphasis added). *Id.* Likewise, our Superior Court in *Lubowitz v. Albert Einstein Medical Ctr., N. Div.*, 424 Pa. Super. 468 , 623 A.2d 3, 5, (1993) held that it was not enough for the plaintiff to establish that there was a chance of exposure to a disease. The plaintiff in *Lubowitz* brought an action because an initial test on the placenta blood used during an in vitro fertilization tested positive for HIV. *Id.* at 4. However, after numerous other tests of both the plaintiff and the donor blood, it was determined the first test was a false-positive, therefore the Superior Court found a cause of action for fear of AIDS could not be maintained. *Id.*

In the instant case, the several tests that were performed on Plaintiff have come back negative. (Complaint, ¶19). Furthermore, Plaintiff has not alleged that the allograft tissue she received was infected. She, much like the plaintiffs in *Lubowitz* and *Burk*, alleges she may have been exposed to disease. (Complaint, ¶61, 65). However, she fails to articulate with specificity which disease(s) that the allograft may have caused her to be infected with.

As our Superior Court explained in *Shumonsky*, both a means of transmission and the presence of the virus must coalesce to establish actual exposure. *Shumonsky*, 784 at

201. The Plaintiff has failed to allege elements sufficient to meet this two-prong test. As to the first element, Plaintiff does not allege that any disease(s) could have been transmitted by allograft supplied by Medtronic and RTI. Nor do these allegations satisfy the second prong, the presence of a “positive” specimen form, which could lead to the conclusion that there is more than a good chance that an infection was transmitted. Thus, Plaintiff did not allege actual exposure, thus her cause of action for negligence must be dismissed. In addition this Court will analyze Plaintiff’s right to seek recovery for the remaining claims of strict liability and breach of warranty.

B. STRICT LIABILITY AND BREACH OF WARRANTY CLAIMS

Plaintiff cannot maintain claims for strict liability, implied warranty, or express warranty against Garzone defendants, RTI and Medtronics because they are immune from liability under Pennsylvania’s Blood Shield law. In her Complaint, plaintiff includes a cause of action against Medtronics and RTI for strict liability for allegedly harvesting, supplying, selling and distributing defective and unsafe human tissue to hospitals (Complaint, ¶54-65, 72-84). In addition, Plaintiff includes actions for breach of expressed warranty and implied warranty of merchantability against Garzone Defendants, RTI and Medtronics claiming Defendants were commercial suppliers of human tissue who sold their product without disclosing that it may have been unsafe or that it was not fit for the its intended purpose. (Complaint, ¶94-106). However, according to 42 Pa.C.S.A. 8333 defendants are immune from strict liability and warranty claims, where the asserted injury arose as a result of transplantation or insertion of tissue and/or bones. 42 Pa.C.S.A. 8333(a), which is also know as Pennsylvania’s “Blood Shield Law” states in pertinent part:

No person shall be held liable for death, disease or injury resulting from the lawful transfusion of blood, blood components or plasma derivatives, or from the lawful transplantation or insertion of tissue, bone or organs, except upon a showing of negligence on the part of such person. Specifically excluded hereunder is any liability by reason of any rule of strict liability or implied warranty or any other warranty not expressly undertaken by the party to be charged.

Thus in Pennsylvania there is a legislative intent to keep blood, human tissue and bone distribution impervious to cause of action sounding in product liability and breach of warranty. The case of *Weishorn v. Miles-Cutter*, 721 A.2d 811 (Pa. Super. Ct. 1998), affirmed by 560 Pa. 557, 746 A.2d 1117, 2000 Pa. LEXIS 703 (2000) demonstrates this principle. The Superior Court in *Weishorn* held that where a blood product recipient was diagnosed with both Hepatitis B and C viruses after receiving a transfusion of Gamimune-N, the commercial blood product supplier, Miles Inc. was shielded from actions for strict liability and breach of warranty under the Pennsylvania Blood Shield Law. The Court also expanded the definition of “person” used in the statute to include corporate entities. *Id.* In their holding, our Superior Court implicitly adopts the Connecticut Supreme Court’s principle rationale for passage of its blood shield statute. Connecticut’s justification for its blood shield statute is that blood, and, in this case, bone and tissue are essential in the medical area and there may never be tests which can guarantee with absolute certainty that blood, bone and/or tissue are uncontaminated with certain viruses. *Id.* at 14. Furthermore, to require providers to serve as insurers of the safety of blood, bone and/or tissue might impose such an overwhelming burden as to discourage the gathering and distribution of them. *Id.*

Accordingly, Plaintiff's actions for strict liability and breach of warranty cannot be sustained as Defendants are immune from liability for these causes of action under the Blood Shield Law.

CONCLUSION

Based on the foregoing analysis, this Court respectfully requests that the October 5, 2006 Orders sustaining Defendants' Preliminary Objections and dismissing all claims against RTI, Garzone Defendants and Medtronic be affirmed by the Court above.

BY THE COURT:

1-14-2008

Date

ALLAN L. TERESHKO, J.

cc:
Aaron J. Freiwald, Esq.
Bruce Bodner
Kate S. McGrath
Murray S. Levin