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HUMAN TISSUE LITIGATION: WHERE IS THE INJURY?

Val Stieglitz and Angelica Colwell summarize trends in litigation arising from transplantation of human tissue, with special focus on the requirement of actual injury.

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Litigation involving the procurement, sale, and implantation of human tissue is increasing. This article will provide a brief overview of developments in this arena.

While the United States Food and Drug Administration ("FDA") has been regulating the human tissue donation industry since 1993, there were no rules prior to 2005 that provided the agency with authority to oversee many of the types of tissues that were involved in the tissue business, or the establishments that were processing the tissues for sale and implantation. However, as advancements in tissue processing expanded the range of tissues that can be used for implantation, and safety concerns pertaining to transmission of infections diseases became more acute, the FDA responded by enacting rules to broaden its authority over the donor tissue industry.

As of May, 2005, rules were in place for the FDA to regulate certain aspects of the recovery, processing, storage, labeling, packaging, and distribution of human cells, tissues, and cellular and tissue-based products, including skin, eyes, musculoskeletal tissue, eggs and sperm, veins, blood stem cells, and the membranous covering of the brain (the dura mater), and practices regarding the prevention of tissue contamination, and the eligibility of potential donors. The donor eligibility rule set forth a process for ensuring that tissues used for transplant had come from an "eligible" donor, as established through medical examinations, testing, review of the donor's records, and interviews of the donor's relatives or close contacts.

Within six months of the enactment of these rules, recalls of human tissue were initiated by several tissue processors, which learned that the procedures of the donor eligibility rule may not have been followed by some of the entities that had procured the tissue that the tissue processors had then processed and put into the marketplace. These recalls prompted the FDA to investigate the practices of one particular human tissue supplier, and ultimately gave rise to criminal indictments of the individuals accused of harvesting the tissue and selling it to the processors, as well as civil lawsuits filed by patients who had received tissues that had been prepared by the processors, which themselves had received tissues from the suspect supplier.

The following will discuss the theories of liability that have been advanced by these patients.

As of October 20, 2006, 324 complaints had been filed by plaintiffs across the United States seeking damages for injuries allegedly arising from donated tissue transplants. The cases had been filed in several federal and state courts. Over 100 of these cases have been consolidated into a Multi-District Litigation case in the District Court of New Jersey.

Very few of the plaintiffs who filed these cases have actually claimed to have contracted a disease from the implanted donor tissue. Where allegations regarding disease were included, hepatitis from implanted tissue was alleged. The vast majority of the plaintiffs alleged no disease, but instead claimed damages relating to fear of contracting disease and ongoing medical

monitoring for the development of disease.

Fear of contracting disease has often been pled as a variant of the generally recognized tort of infliction of emotional distress. This claim generally requires exposure to physical peril or injury, resulting from the defendant's conduct. Most jurisdictions that have considered claims for fear of contracting disease have looked to the physical peril or injury requirement to bar recovery. Proof of exposure to disease has been considered an essential element to the fear of contracting disease claim. At least one case filed ten years before the FDA even began exerting any regulatory authority over the donor tissue industry denied damages to a plaintiff who could not show actual contamination of the donor tissue that had been received. *Nesom v. Tri Hawk Intern*, 985 F.2d 208 (5th Cir. 1983). There, the Fifth Circuit Court expressed concern that permitting the claim would "open the door to thousands" claiming damages caused by fear of *possible* exposure *Id.* at 211 (emphasis added).

The plaintiffs in the recently-filed tissue litigation cases have also based their claims for recovery on an alleged need for medical monitoring for the development of disease. Here again, however, the lack of any physical peril or injury has been the undoing of most of the claims.

Several of the defendants in the currently pending Multi-District Litigation claims, Regeneration Technologies, Inc., Medtronic, Inc., Medtronic Sofamor Danek USA, Inc., and Spinalgraft Technologies, LLC, have moved for summary judgment on all claims on the grounds that the plaintiffs cannot establish causation, another "traditional tort element." As argued by these MDL Defendants, there are two levels of causation that must be shown to establish a tort claim: general causation, which requires a showing that a hazardous substance is capable of causing a particular injury, and specific causation, which requires proof that the substance caused the particular injury claimed by the plaintiff. These MDL Defendants have argued that the plaintiffs' cases fail at the general causation step of the analysis because reliable scientific evidence demonstrates that the processing method used by the moving Defendants achieves a sterility level in the donor tissue that has never been reported to have caused disease after implantation.

Framed in this fashion, the scientific evidence proffered by the MDL Defendants contradicts the plaintiffs' allegations that they were actually exposed to disease in any of the tissue that was processed by the aforementioned Defendants prior to implantation. While these Defendants may have received tissue from the supplier that is under the investigation of the FDA, then processed and sold that tissue, the plaintiffs have not only failed to show any existing physical injury from the tissue, but have also failed to link any action by the supplier with any actual disease occurrence in a plaintiff.

Other claims which have been filed in the current tissue litigation include claims for battery and product liability. Battery, as every first year law student learns, is a tort cause of action arising from a harmful or offensive contact with his or her person. In the present context,

the plaintiff must show exposure to some disease-causing factor as a result of the transplant.

Finally, strict liability claims have also been filed by plaintiffs receiving the transplanted tissues. While strict liability eliminates the requirement for a plaintiff to prove fault by the manufacturer or seller of the product, it still requires proof of a defective condition in the product, that was unreasonably dangerous to the user, and which caused injury. Such a defective condition would be contamination of the tissue after processing, with factors known to cause disease. These factors might be from outside contamination, or ineffective processing that fails to eliminate disease factors present in the tissues. However, a plaintiff lacking any physical injury whatsoever would not meet this requirement.

Some tissue litigation plaintiffs have asserted warranty claims. These claims sound in contract. While causation requirements may be eased in such claims – a plaintiff is not necessarily required to produce direct evidence of the cause of the defective condition – the plaintiff will still have to establish the defective condition of the product. In short, a warranty-based cause of action does not eliminate the need to show contamination of the donor tissues.

While the cases discussed above involve tissues and not blood products, it is possible that some State "blood shield statutes," limiting liability for claims involving blood and blood products, could be extended to procurement, processing, and/or sale of human tissues for transplant. This will be a state-by-state determination, but should not be overlooked from the defense standpoint.