

## Strict Liability Does Not Apply to Medical Devices

November 26, 2011 by [Sean Wajert](#)

Another court has recognized that strict liability or breach of implied warranty claims do not lie against medical device makers. [Horsmon v. Zimmer Holdings Inc.](#), No. 11-1050 (W.D. Pa., 11/10/11).

Plaintiff had a total hip replacement whereby her right hip joint was replaced with implant components designed, manufactured, and sold by defendants. Ms. Horsmon alleged she later began to experience pain in her right hip, which eventually required further surgery. She alleged this was due to a defect in the original liner that was used during the hip replacement. She sued, and defendants moved to dismiss.

Defendants asserted that plaintiff's claim for strict liability was barred by Pennsylvania law. The Supreme Court of Pennsylvania in *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), held that strict liability claims cannot be brought against prescription drug manufacturers. The court relied on Comment k to the Restatement (Second) of Torts § 402A, regarding unavoidably unsafe products. The Superior Court of Pennsylvania and several United States District Courts applying Pennsylvania law have extended *Hahn* to bar strict liability claims against medical device manufacturers. E.g., *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006). This court agreed that the reasoning of *Hahn* extends to medical devices.

Defendants further asserted that plaintiff's breach of implied warranties claim was also barred by Pennsylvania law. In a claim for breach of implied warranty of merchantability, the essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used. Under Pennsylvania law, the very nature of prescription drugs precludes the imposition of a warranty of fitness for ordinary purposes, as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient. Breach of implied warranty of merchantability claims, therefore, are precluded for prescription drugs. Again, several courts have extended this reasoning to preclude claims against medical device manufacturers for breach of implied warranties of merchantability and fitness for a particular purpose. And the district court here agreed; there was no compelling reason to distinguish between prescription drugs and medical devices.

The court then turned to the express warranty claim. Under Pennsylvania law, any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. Here, plaintiff alleged that defendants expressly warranted in written literature, advertisements and representations of representatives and agents that the systems, bone screws, liners and other related components were safe, effective, fit, and proper for the use for which they were intended. But plaintiff did not allege any particular affirmation of fact or promise, as required under federal pleading rules, that would give rise to a reasonable inference that defendants expressly warranted that its products were safe, effective, fit, and

proper for the use for which they were intended. Plaintiff failed to allege that any particular affirmation of fact or promise was made in any of those sources. Plaintiff's allegations also did not support a reasonable inference that any affirmation of fact or promise by defendants became part of the basis of the bargain in plaintiff's purchase. (Of course, plaintiff could not allege that any particular affirmation of fact or promise became "part of the basis of the bargain" without alleging any particular affirmation of fact or promise.) Thus, plaintiff failed to state a plausible claim for breach of express warranties under Pennsylvania law. (However, the court gave Horsmon another chance to amend and replead her breach of express warranty claim.)