Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

Raising the Bar for Design Defect Claims: A New Jersey Judge Puts Plaintiffs' Feet to the Fire

On August 14, 2015, the Honorable Jessica R. Mayer issued numerous rulings in four bellwether cases in the AlloDerm® Litigation, a multi-county litigation pending in New Jersey Superior Court in Middlesex County. Most notably, Judge Mayer dismissed plaintiffs' design defect claims for failure to proffer reliable expert testimony showing that plaintiffs' proposed alternative designs were feasible and safer at the time of plaintiffs' surgeries. Memorandum of Decision on Defendant's Motions for Partial Summary Judgment as to Plaintiffs' Claims for Design defect, *In Re: AlloDerm® Litigation*, Case Code 295 (Aug. 14, 2015).[1]

AlloDerm Regenerative Tissue Matrix ("AlloDerm®") is a banked human tissue graft product developed, manufactured and marketed by the New Jersey firm LifeCell. AlloDerm® is used to remodel tissue into a range of functional tissues in the human body that provide structural support, including hernia repair. All four bellwether plaintiffs had incisional hernias repaired with AlloDerm®, had hernia recurrence, and required additional surgery. Plaintiffs brought suit under the New Jersey Products Liability Act ("NJPLA"), *N.J.S.A.* § 2A:58C-1, *et seq.*, alleging that AlloDerm® was defectively designed and unfit for use in abdominal hernia repairs due to thinning and stretching, leading to abdominal bulging and hernia recurrence, necessitating additional surgeries.

1. Judge Mayer's decision can be accessed online at http://www.judiciary.state.nj.us/mass-tort/alloderm/sum-judge-plainit-design-defect.pdf.

Sept
2015

In support of its motion to dismiss, LifeCell argued that a plaintiff in a design defect case is required under New Jersey law to prove the existence of evidence of a safer alternative design and that plaintiffs failed to present sufficient evidence that a safer alternative design existed at the time of their respective surgeries. In opposition, plaintiffs argued that a safer alternative design was not a necessary element of their *prima facie* case for design defect, but that they nonetheless presented sufficient evidence to demonstrate one. Plaintiffs also argued that LifeCell's failure to alter the design or conduct testing to determine if AlloDerm® was appropriate for use in hernia repairs rendered the product defective, and that plaintiffs were not required to show that a safer alternative design existed at the time of plaintiffs' surgeries (as opposed to the time of trial).

In dismissing plaintiffs' design defect claims, Judge Mayer concluded that a feasible and safer alternative design is not merely a factor to be considered in the risk-utility analysis—it is an element of a plaintiff's *prima facie* case, except in rare cases where a product is so dangerous that under the risk-utility analysis the manufacturer should bear the costs of liability or harm to others. *See Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 571 (1998); *Diluzio-Gulino v. Daimler Chrysler*, 385 N.J. Super. 434, 438 (App. Div. 2006); *Smith v. Keller Ladder Co.*, 275 N.J. Super. 280, 283-84 (App. Div. 1994). Judge Mayer made clear that in cases where the defendant does not raise the state-of-the-art defense, *N.J.S.A.* § 2A:58C-3(a)(1), and instead attacks the practicality of a plaintiff's proposed alternative design, "the plaintiff must prove either the existence of a reasonable alternative design or, that even though no safer alternative existed, the product was so egregiously dangerous and of so little use that the manufacturer should nonetheless be held liable." *Cavanaugh v. Skil Corp.*, 164 N.J. 1 (1999); *N.J.S.A.* § 2A:58C-3.

Relying on *Jones v. Synthes U.S.A. Sales, Inc.*, 2010 U.S. Dist. LEXIS 85744 (D.N.J. Aug. 19, 2010), Judge Mayer held that "[a] plaintiff's burden of proving a feasible and safer alternative design requires expert testimony." Judge Mayer also ruled that "in cases involving complicated products or design specifications, the expert's opinion must be supported by empirical evidence or specific data to provide the jury with a reasonable basis for concluding that a plaintiff's proposed alternative is actually safer than the allegedly defective product." *See Diluzio-Gulino*, 385 N.J. Super. at 438; *Rider v. Twp. Of Freehold*, 2008 N.J. Super. Unpub., LEXIS 641 (App. Div. July 14, 2008).

Based in part on plaintiffs' own experts, who opined that AlloDerm® was useful in certain circumstances for hernia repair, Judge Mayer concluded that AlloDerm® is not so "egregiously dangerous and of so little use that Plaintiffs may prove a design defect without proving the existence of a safer alternative design." Accordingly, Judge Mayer considered whether plaintiffs established the existence of a feasible and safer alternative design.

Plaintiffs argued that scientific evidence established the existence of three feasible and safer alternative designs. The first was a product developed by LifeCell called Strattice®, a graft made out of pig skin. Judge Mayer rejected this argument because there was inadequate scientific evidence supporting the product's safety. Plaintiffs cited a 2010 study which concluded that Strattice® "may be an attractive alternative" to AlloDerm®. Judge Mayer, however, discounted this study because it was based on the anecdotal experiences of the article's authors and was not supported by any empirical evidence. Moreover, the study was not published until after each of the plaintiffs' implant surgeries. Plaintiffs also pointed to a 2004 article suggesting that AlloDerm® made with pig skin Strattice® might be a feasible alternative to synthetic meshes. Judge Mayer held that this study did not demonstrate that such an alternative was feasible or safer at the time of plaintiffs' surgeries and did not take into account the time required for FDA approval.

The second alternative design plaintiffs proposed was optimization of AlloDerm® through cross-linking (chemically treating the graft to increase its strength) or better controlling thickness levels of the graft. Judge Mayer concluded that plaintiffs had not established that this was a safer alternative design because plaintiffs' experts had not conducted any testing to establish how or to what extent AlloDerm® could be cross-linked to improve the product, or that a thicker graft would be safer.

Finally, plaintiffs asserted that cross-linked animal-based grafts provide a safer alternative design, pointing to Permacol® as an example. Permacol® is a cross-linked porcine pig skin based product that has been commercially available since 2002. Plaintiffs pointed to three studies demonstrating the safety of Permacol®. However, since none of the three studies were published until after plaintiffs' surgeries, and plaintiffs' experts were unable to cite to any other supporting medical literature or empirical data which pre-dated two surgeries, Judge Mayer concluded that plaintiffs failed to show that Permacol® was safer than AlloDerm®.

In addition, Judge Mayer rejected plaintiffs' argument that failure to test AlloDerm® and failure to specifically consider hernia repair in its design of AlloDerm® constituted design defect. Citing *Green v. General Motors Corp.,* 310 N.J. Super. 507, 529 (App. Div. 1998), Judge Mayer concluded that "[a] lack of testing or a flaw in the design process is not, standing alone, a design defect." Judge Mayer also disagreed with plaintiffs' argument that the relative safety of the alternative design is to be assessed based on scientific evidence and available alternative products in existence at trial. Quoting *Lewis*, 155 N.J. at 565, Judge Mayer observed that "Defendants in products liability actions should be judged not on what occurs in the future, but on what they

knew or should have known at the time their products left their control."

Ultimately, since plaintiffs failed to present expert testimony demonstrating a feasible and safer alternative design, plaintiffs' design defect claims were dismissed.

What Does This Ruling Mean?

Judge Mayer's dismissal of plaintiffs' design defect claims was based on plaintiffs' failure to prove the existence of a feasible and safer alternative design. While this is not a new concept in New Jersey law, it may be the first time it has been applied in the life sciences context and in a multi-county litigation. In light of this ruling, a plaintiff who pursues a design defect claim in a life sciences case faces a tough burden to show that an alternative design existed because the plaintiff must put forward empirical data to show that a proposed alternative design was not only technologically feasible and practical at the time of manufacture, but was actually safer than the device plaintiffs used and that there was evidence that the alternative design was safer at the time of the manufacture (as opposed to at the time of trial).

We will continue to keep you apprised of further developments in this area.

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