# Products Liability: The Swinging Pendulum

Many federal district courts which have addressed the question, whether products liability cases against medical device manufacturers are preempted by the Federal Food and Drug Act have expressed some reluctance to permit patients to go forward with such lawsuits, even in the post-*Tincher* context. The Third Circuit proved itself wrong previously when it predicted that the Pennsylvania Supreme Court would follow the American Law Institute Restatement Third on Products Liability. *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 104 A.3d 328 (2014), rejected the negligence language in the Restatement Third and determined that Pennsylvania products liability law would continue to adhere to the Restatement Second, Section 402A, with the modification that the jury rather than the judge would consider alternative safety design, risks and rewards of a particular design and that consumer expectations would be a factor to be determined by the jury.

In a thoughtful and important opinion, Judge Baylson of the Eastern District of Pennsylvania wrote that medical products can be subject to strict liability lawsuits, including such "devices" as pelvic mesh. *Gross v. Coloplast Corp.*, No. 19-4385, 2020 U.S. Dist. LEXIS 8183 (E.D.Pa. January 17, 2020)(Baylson, J.). Comment k to § 402A would not exempt medical devices. The court distinguished *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), as well as *Creazzo v. Medtronic*, 903 A.2d 24 (Pa. Super. 2006), based upon the developing case law subsequent to *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 104 A.3d 328 (2014), noting that the Pennsylvania Supreme Court in *Tincher* has cautioned Pennsylvania courts against making categorical carveouts from the presumption of strict liability. Defendant's motion to dismiss was denied.

The Rieders Travis Law Firm, thanks to the work of Attorneys Sasha Coffiner and Pam Shipman, posted a major victory in *Gross* in connection with pharmaceutical medical device litigation. There has been ongoing debate in the law as to whether medical devices are entitled to immunity based upon Federal Food and Drug Administration preemption.

Preemption does exist in the pharmaceutical field, but it has not been uniformly applied to protect manufacturers of medical devices. The Rieders Travis lawyers successfully argued that the legal landscape has been altered since the landmark product liability case of *Tincher vs. Omega Flex*, 104 A.3d 328 (Pa. 2014), which disapproved of "carving out certain categories of products for special treatment within the common law of products liability." *Gross* at *7. *Tincher* at 104 A.3d, 396 and *Lance vs. Wyeth*, 85 A.3d 434 (Pa. 2014), cautioned against "thoughtlessly extending" into other areas a decades old prohibition against strict liability claims with respect to prescription drugs. The Judge in *Gross* accepted the rationale urged by Firm attorneys that Pennsylvania law is moving in the direction of permitting products liability claims to be pursued against manufacturers of medical devices, and allowed the strict liability cause of action in the

case to proceed. The Judge in *Gross* accepted the rationale urged by Firm attorneys that Pennsylvania law is moving in the direction of permitting products liability claims to be pursued against manufacturers of medical devices, and allowed the strict liability cause of action in the case to proceed. See also *Schrecengost v. Coloplast., Corp*., 2019 U.S. Dist. LEXIS 206855 (E.D. Pa. December 2, 2019)(Gibson, J.)(adopting similar rationale).

The takeaway bullet points from *Gross* are as follows:

- Plaintiff sued Coloplast.
- 12(b)(6) motion denied.
- The mesh was approved through the FDA's § 510(k) process.
- FDA ordered Coloplast to stop selling and distributing this and other products because of safety and effectiveness issues.
- Pennsylvania law would permit a strict liability case to go forward.
- The court distinguished *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996).
- The court also distinguished *Creazzo v. Medtronic*, 903 A.2d 24 (Pa. Super. 2006).
- *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 104 A.3d 328 (2014), as well as *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), discourage Pennsylvania courts from making categorical decisions, especially on limited record, especially based on comment k of 402A.
- *Creazzo* is not persuasive of how the Pennsylvania Supreme Court would rule.
- *Tincher* stands for the proposition that there should not be categorical exclusions from strict liability.

No doubt, the *Gross* opinion will represent either a turning point or yet another judicial position in the ongoing judicial debate concerning federal preemption in the medical device field. Sooner or later, the Pennsylvania Supreme Court will speak on the subject.