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US Judge, Weighing 'Tincher,' GreenLights Strict Liability Claims Against Med Device Maker

ESPECIALLY AT THE MOTION TO DISMISS PHASE, U.S. DISTRICT JUDGE MICHAEL BAYLSON OF THE EASTERN DISTRICT OF PENNSYLVANIA SAID IT MADE MORE SENSE TO ALLOW THE STRICT LIABILITY CLAIMS TO PROCEED.

By Max Mitchell | January 21, 2020 at 04:58 PM

In a decision wading into the ramifications of the Pennsylvania Supreme Court's seminal decision in *Tincher v. Omega Flex*, a federal judge has rejected efforts to carve out an exception to strict liability law for the makers of prescription medical devices.

On Jan. 16, U.S. District Judge Michael Baylson of the Eastern District of Pennsylvania rejected efforts by medical device company Coloplast seeking to toss the strict liability claims from the case *Gross v. Coloplast*. The ruling denied the company's motion to dismiss for failure to state a claim on the strict liability issues.

Coloplast had sought to expand protections afforded to the makers of prescription drugs under comment K to Section 402 of the Restatement (Second) of Torts, citing the 2006 Pennsylvania Supreme Court decision in *Creazzo v. Medtronic*. But, in his 11-page ruling, Baylson said that, under the more recent *Tincher*, the Pennsylvania Supreme Court has advised judges not to make categorical decisions about products with regard to liability.

"The Pennsylvania Supreme Court has strongly discouraged Pennsylvania courts from carving out certain categories of products for special treatment within the common law of products liability," Baylson said, citing *Tincher*.

[Rieders, Travis, Humphrey, Waters & Dohrmann](#) attorney Clifford Rieders

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(<https://www.law.com/thelegalintelligencer/2019/12/05/certificates-of-merit-and-vicarious-liability-claims/>) said that, although district courts in Pennsylvania have previously waded into the issue, Baylson’s ruling provides the first in-depth analysis on whether comment K should be expanded in the wake of *Tincher*.

“What *Tincher* said, and what product liability law said, is you don’t categorize between products. That puts the court in the role of making public policy,” Rieders said. “There’s no basis, under *Tincher*, for artificial distinctions.”

Morgan, Lewis & Bockius attorney Wendy West Feinstein, who is representing Coloplast, did not return a call seeking comment.

According to Baylson, Crystal Gross and her husband Timothy Gross sued Coloplast over its allegedly defective pelvic mesh device in 2018. Baylson noted that the U.S. Food and Drug Administration initially approved the device, but ordered the company to stop selling it in April 2019. The Grosses raised eight claims, including three based on strict liability.

Coloplast led a motion to dismiss several causes of action, arguing that the plaintiffs failed to make a claim.

Baylson explained that comment K to Section 402A exempts certain “unavoidably unsafe products” from strict liability claims, and that in 1996, the Supreme Court adopted the comment with regard to strict liability claims involving prescription drugs. That ruling came in *Hahn v. Richter*.

Coloplast, according to Baylson, argued that *Creazzo*, in which the Superior Court extended *Hahn* to encompass prescription medical device makers, indicates that the Supreme Court is likely to extend comment K protections to prescription devices. But Baylson rejected that argument.

According to Baylson, in the wake of *Creazzo*, the Supreme Court has specifically cautioned against

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“lightly altering the common law of products liability,” and that subsequent Supreme Court rulings have noted Hahn was based on a “rather one-dimensional analysis” that “offers a poor foundation for extrapolation.”

Especially at the motion to dismiss phase, Baylson said it made more sense to allow the strict liability claims to proceed.

“The Pennsylvania Supreme Court has cautioned Pennsylvania courts against making categorical carveouts from the presumption of strict liability without, at the least, a rich factual record on the policy issues that should inform a common law analysis of whether to allow these claims,” Baylson said.