Sills Cummis & Gross P.C.

Client Alert Product Liability Law

New Jersey Appellate Division Finds that Evidence of 510(k) Clearance Cannot be Categorically Excluded in Medical Device Product Liability Cases

FDA clears the vast majority of medical devices for marketing through the 510(k) process. In product liability cases involving 510(k) medical devices, plaintiffs often seek to exclude 510(k) evidence from trial based on arguments that: (1) the 510(k) process is less rigorous than the pre-market approval (PMA) process, and does not include the FDA's independent evaluation of safety and efficacy; (2) the jury may place undue emphasis on the FDA's 510(k) clearance; and (3) admission of the evidence leads to mini-trials on the meaning and significance of the 510(k) clearance. Device manufacturers typically oppose the exclusion of 510(k) evidence because it unfairly prevents them from explaining to the jury the regulatory requirements and framework that dictate their decision making. In a published opinion, *Hrymoc v. Ethicon, Inc.*, 2021 N.J. Super. Unpub. LEXIS 337 (N.J. App. Div. Mar. 2, 2021), the New Jersey Appellate Division recently reversed and remanded two plaintiffs' verdicts in the New Jersey pelvic mesh multi-county litigation, finding that the trial court improperly excluded 510(k) evidence from the liability and punitive damages phases of the trials. While stopping short of requiring the trial judge to admit 510(k) evidence, the Court's opinion made clear that wholesale exclusion of such evidence denied manufacturers the right to a fair trial. Recognizing that the trial court's decision could potentially impact the entire MCL, the Court recommended that a single judge hold a Rule 104 hearing to set the framework for admission of 510(k) evidence in future New Jersey pelvic mesh trials.

Trial Court Proceedings

Hrymoc involved a consolidated appeal of two separate jury verdicts rendered in the New Jersey pelvic mesh litigation in 2018. The *Hrymoc* case involved Ethicon's Prolift pelvic mesh device. The *McGinnis* case involved two pelvic mesh devices designed and manufactured by C.R. Bard. All of the pelvic mesh devices at issue in *Hrymoc* and *McGinnis* were Class II medical devices FDA cleared through the 510(k) process. Under the 510(k) process, the FDA can clear a product for marketing if the product is found to be "substantially equivalent" to a product already on the market.

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Hrymoc involved a New Jersey plaintiff who brought product liability claims against Ethicon under the New Jersey Product Liability Act (PLA). *McGinnis* involved a North Carolina plaintiff, who brought product liability claims against Bard under North Carolina law. Plaintiffs in both cases sought punitive damages, which the courts decided under New Jersey law. Both the *Hrymoc* and *McGinnis* cases were tried by two different trial court judges before different juries in the New Jersey Superior Court, Bergen County. In both cases, plaintiffs moved *in limine* to preclude Ethicon and Bard from introducing evidence that FDA had cleared the devices for marketing through the 510(k) process. The trial court in *Hrymoc* granted plaintiff's motion and precluded Ethicon from telling the jury, during the liability and punitive damages phases of the trial, that the Prolift device had received FDA 510(k) clearance, because it held that such clearance did not equate to a finding by the FDA of the product's safety and efficacy.

The trial court in *McGinnis* reached the same conclusion under North Carolina law. Although North Carolina has a statute that requires the submission of government standard evidence during a product liability trial, the *McGinnis* trial court held that the 510(k) clearance process was not a government standard because it did not result in a finding of the device's safety and efficacy. The *McGinnis* court also held that Bard's 510(k) evidence was also excludable under *N.J.R.E.* 403 because any probative value of the evidence was substantially outweighed by potential prejudice and juror confusion. The *McGinnis* trial court held that admission of 510(k) evidence would result in a mini-trial on the meaning and strength of the 510(k) clearance process, which had the potential to prolong the trial and confuse the jury, even with a limiting instruction.

In *McGinnis*, Bard also moved for summary judgment on plaintiff's punitive damages claim under the PLA, which precludes punitive damages claims in cases involving products that are approved, licensed, or generally recognized as safe by the FDA. The *McGinnis* trial court denied the motion, rejecting Bard's argument that 510(k) clearance constituted approval, licensure, or a general recognition of safety by the FDA. Prior to the punitive damages phase of the trial, Bard moved to admit 510(k) evidence in response to plaintiff's punitive damages claims. The trial court denied Bard's motion for the same reasons it precluded the 510(k) evidence from the liability phase of the trial.

In *Hrymoc*, the jury found in plaintiffs' favor on their design defect and failure to warn claims, and awarded plaintiffs $5M in compensatory damages and $10M in punitive damages. The jury in *McGinnis* also found in plaintiffs' favor on their design defect and failure to warn claims and awarded plaintiffs $33M in compensatory damages and $35M on their punitive damages claim.

The Appellate Division's Decision

Both Ethicon and Bard filed appeals seeking to overturn the jury verdicts in *Hrymoc* and *McGinnis* on various grounds. The defendants' primary argument was that the trial courts erred when they excluded all 510(k) evidence from both the liability and punitive damages phases of the trials. Ethicon and Bard argued that exclusion of 510(k) evidence during the liability phase of the trials prejudiced their defense to plaintiffs' liability claims

because they were precluded from explaining to the jury that they made certain product decisions in compliance with FDA regulations. For example, although plaintiffs roundly and regularly criticized Ethicon and Bard for their failure to conduct clinical trials, the defendants were precluded from explaining the 510(k) process to the jury, and that FDA regulations did not require manufacturers to conduct such trials for the devices at issue. Ethicon and Bard also argued that exclusion of 510(k) evidence during the punitive damages phase of the trial deprived them of their ability to explain the decision making behind their conduct.

The Appellate Division agreed with Ethicon's and Bard's arguments that the trial courts' exclusion of 510(k) evidence deprived the defendants of a fair trial during both the liability and punitive damages phases of the trials. The court began its analysis by canvassing how courts in other jurisdictions addressed the admissibility of 510(k) evidence in medical device cases. Because it concluded that federal courts had split on the issue, the *Hrymoc* court conducted an independent review.

The court first noted that 510(k) clearance is "not a plenary determination of that device's safety and effectiveness," and merely represents the FDA's finding of a device's substantial equivalence to a predicate device. Nonetheless, the court found that 510(k) evidence shows that the manufacturer obtained regulatory authorization to market the product and therefore, such evidence did have "probative value in evaluating the company's design and sale of the devices." The court explained that in evaluating whether the probative value of Ethicon's and Bard's 510(k) evidence was substantially outweighed by factors under *N.J.R.E.* 403, required an analysis of the evidence that was presented at trial. The court noted that plaintiffs in both *Hrymoc* and *McGinnis* presented evidence and arguments that the defendants never conducted clinical trials on their devices. The court explained Ethicon and Bard should have been permitted to counter plaintiffs' evidence and arguments with evidence about the 510(k) process and the fact that the FDA did not require manufacturers of such devices to conduct clinical studies to support a 510(k) application.

The court determined that the unfairness of the exclusion of the evidence was particularly pronounced during the punitive damages phase of the trials, because the defendants were precluded from presenting evidence that explained the reasons for their decisions. Although the court did not find that the PLA mandates the admission of 510(k) evidence in every medical device trial, the court expressed substantial concerns that exclusion of such evidence had the potential for jurors to improperly presume that the defendants marketed and sold their products without any regulatory clearance or oversight.

The court held that the fairest approach was for the trial court to explore "whether a limited amount of 510(k) information, through a well-crafted stipulation or a modest presentation of evidence from both sides, along with a cautionary instruction from the judge could help assure a fair trial." For example, the court could limit the number of witnesses or time allotted to the topic. The trial court could also consider utilizing a limiting instruction that explains the regulatory differences between 510(k) and PMA devices in a neutral manner, including that 510(k) devices are only evaluated for substantial equivalence

and do not require an independent evaluation of the device's safety and efficacy. Other potential considerations included precluding certain arguments or eliminating the use of demonstrative aids. With these potential measures, the court held that 510(k) evidence can be effectively presented to the jury without causing confusion or devolving into mini-trials on the issue. The court concluded that "[a]ll of these matters are best addressed by the trial court in a fulsome pretrial Rule 104 proceeding."

Because the trial courts had not properly considered the prejudicial effect the exclusion of 510(k) evidence had on Ethicon's and Bard's ability to defend against plaintiffs' product liability and punitive damages claims, the court vacated the jury verdicts and remanded the cases for new trials. The Appellate Division noted that the trial courts were not categorically required to admit 510(k) evidence at the new trials, but should conduct Rule 104 hearings during which they "deeply reconsider" the exclusion of such evidence, especially during the punitive damages stage of the trials.

Lastly, the Appellate Division rejected Bard's arguments that the PLA precluded punitive damages claims in product liability cases involving 510(k) medical devices. The court reasoned that 510(k) clearance did not include the FDA's independent evaluation of the devices safety and efficacy and therefore, did not constitute a finding of the FDA's approval or licensure of the device, or that the device was generally recognized as safe.

What Does This Case Mean?

Although the Appellate Division stopped short of holding that 510(k) evidence must be admitted in all medical devices cases involving 510(k) products, the Appellate Division's decision contains strong language that such evidence has probative value, and that the exclusion of such evidence has a high potential to deprive medical device manufacturers of a fair trial against product liability and punitive damages claims. The decision also strongly encourages trial courts to explore all other measures short of excluding the evidence, including conducting Rule 104 hearings, limiting the amount and type of evidence, and using limiting instructions, in order to eliminate any potential concerns raised by the admission of such evidence. Plaintiffs in the *Hrymoc* and *McGinnis* cases have appealed the decision to the New Jersey Supreme Court. We will continue to keep you apprised of further developments in this important area.

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