Legal Opinion Letter

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IT'S TIME TO STOP BLINDFOLDING JURIES IN MEDICAL DEVICE CASES

by Phil Goldberg

The New Jersey Supreme Court has agreed to hear a pair of cases that will have a major impact on medical device liability and, in turn, the availability of important new devices that offer technological advances over previous products. The issue is over the admissibility of evidence that the manufacturer received the U.S. Food and Drug Administration's (FDA) clearance before bringing the device to market. Plaintiffs' lawyers want juries to decide core liability issues—whether a medical device is defective or its manufacturer should be subject to punitive damages for how it brought the device to market—as if the FDA did not exist.

The cases before the New Jersey Supreme Court are *McGinnis v. Bard* and *Hrymoc v. Ethicon*. Both involved pelvic mesh devices implanted into women now alleging complications. In both cases, the trial courts agreed with the plaintiffs' lawyers and withheld information from the juries that the FDA cleared both devices for implantation. Bard, for example, received FDA clearance in 2007 after submitting scientific data, animal testing, biocompatibility results, and warnings including of the harms alleged. In both cases, trials led to multi-million dollar verdicts for the women and punitive damages against the companies.

The New Jersey Appellate Division, in a lengthy ruling, held the trial courts "erred by categorically excluding" this evidence. Understanding how a device was brought to market includes the FDA's role in permitting the manufacturer to market it: "the total disallowance of such proof had the patent capacity to deprive defendants of a fair trial, most poignantly with respect to the state-of-mind and venal conduct issues that underlie the punitive damage awards."

The court also explained that withholding this information undermines the juries' ability to do their jobs. Here, the plaintiffs' lawyers "unfairly and repeatedly capitalized" on the exclusion of this evidence by arguing Bard and Ethicon did not do "needed" or "clearly required" studies before bringing the devices to market. The companies "should have been able to counter them by allowing the jurors to at least know . . . the fact that the FDA did not require" these studies. As a result, the juries in each case had a "skewed impression" of the facts.

In issuing this ruling, the New Jersey Appellate Division joined a growing number of courts allowing juries access to this information, generally referred to as "510(k) evidence" after the corresponding provision in the federal code. But they are doing so in the face of precedent from federal appellate courts that judges can deny juries this information. As this Legal Opinion Letter explains, these precedents are outdated, and the New Jersey Supreme Court should follow its Appellate Division in taking a fresh look at this evidentiary question.

What is FDA's 510(k) Process for Medical Devices? Congress enacted the Safe Medical Devices Act in 1990 to provide FDA with a robust path for permitting a manufacturer to market a medical device when the device does not need to go through the Pre-Market Approval (PMA) process. These devices are generally Class II medical devices, which is the mid-tier of risk, and often represent technological advances over existing devices. The overwhelming majority of medical devices in the United States enter the market through this process, defined in section 510(k) of the Food Drug & Cosmetic Act.

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Congress's goal in providing the FDA with this alternative to the PMA was to give the FDA flexibility in how it gives the public access to new devices. The FDA first determines whether a device is a Class I, Class II or Class III device (often after convening panels of medical and scientific professionals) and then decides whether the device is assigned to the 510(k) process or the PMA process. Importantly, the FDA—not the manufacturer—makes these decisions.

For 510(k) devices, the crux of the FDA's review is to ensure the device is "substantially equivalent in safety and efficacy" to an existing or "predicate" device. The manufacturer must show the new device is intended for the same use as the predicate and the advancements do not raise different probable benefits and risks as the predicate. It also must show the new device is *at least as safe and effective* as the predicate.

The FDA has repeatedly stated that the 510(k) process is a safety and efficacy review. For example, in a 2014 guidance FDA affirmed that "principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review."

Why Is Admissibility of FDA 510(k) Evidence Controversial? Courts are increasingly determining that evidence related to FDA's 510(k) process is admissible: this information is relevant and probative as to whether a device is defective in design and/or a manufacturer should face punitive damages over its decision to market the device. In the past, some courts have excluded this evidence. Why?

First, they have an outdated view of the 510(k) process from the U.S. Supreme Court's ruling in *Medtronic v. Lohr*. *Lohr* does not apply to this situation for two reasons. In that case, the Supreme Court analyzed the 510(k) process as it existed in the 1980s—before the 1990 Safe Medical Devices Act converted the 510(k) process into a safety and efficacy review. And, the Court assessed whether the express preemption provision for devices approved through the PMA process applied to 510(k) devices—a different question from admissibility of evidence. The Court held the 1980s' version of the 510(k) process was not a sufficient safety review to warrant federal preemption.

The Court was not wrong. In the 1980s, 510(k) had an entirely different purpose, namely to grandfather some devices from before the 1976 Medical Device Amendments gave FDA oversight over medical devices. Old devices could stay on the market and new iterations could be marketed if substantially equivalent to the predicate device. The 1990 Safe Medical Devices Act changed the entire objective and structure of 510(k). So, *Lohr* has no bearing on today's 510(k) process or whether it is an admissible safety regulation.

Second, plaintiffs' lawyers have leveraged terminology differences: the FDA "clears" a device under 510(k) and "approves" it under PMA. These words—clearance and approval—reflect the different processes, but do not undermine the FDA's oversight. The average 510(k) submission is 1,185 pages and takes six months to review. The FDA regularly asks for more information, including studies, and rejects nearly a third of all 510(k) applications. Thus, regardless of terminology, the process the FDA uses to permit a manufacturer to market a medical device is relevant and probative to questions over how the device was brought to market.

Third, courts have said admitting this evidence could be confusing and take up time at trial. As the New Jersey court explained, these concerns "can be capably addressed by the trial court through appropriate means," including limiting instructions. Several trials, including bellwether cases in the IVC filter multidistrict litigation, have proven this point. The greater concern, the court found, is the prejudice to a manufacturer from not being able to explain to a jury why it made certain decisions in bringing a device to market. Courts often trust jurors with regulatory information and limiting instructions in product liability cases and "[w]e should not underestimate the intelligence and conscientiousness of jurors" to do so here.

One factor juries should be able to consider, for example, is whether the FDA, in clearing a medical device, was balancing the needs of the entire population given that a device may work for most people, but not everyone. If this and other voids in FDA's decision-making are filled with plaintiff-lawyer rhetoric, hindsight bias, and sympathy, a jury is more likely to find a device is defective, regardless of whether that finding is accurate. The risk is that such a finding will end up depriving the broader public of the important benefits the medical device provides.

In *McGinnis* and *Hrymoc*, the New Jersey Supreme Court has an opportunity to cement the new line of cases. Trial courts can trust jurors with 510(k) evidence, including why FDA required some tests, but not others, or why the device's warnings did or did not contain certain information. Only then can juries properly facilitate the pursuit of justice.

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