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Use of Pre-Clearance FDA Authorization Evidence in Medical Device Litigation

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Medical device manufacturers may soon receive good news from the U.S. Supreme Court. When the Court starts its next session, it will decide whether to review a product liability lawsuit, *Ethicon v. Huskey*, that poses this essential question: may a medical device manufacturer introduce evidence related to the U.S. Food and Drug Administration's (FDA) premarket review and clearance of a medical device in a case where a consumer alleges the device is defective and unsafe? The chance to address this question comes at a critical time because lower courts recently have been preventing medical device companies from introducing such evidence.

In regulating the sale of medical devices, the FDA places the devices into one of three risk-based classes, each of which places different requirements on the manufacturer to reasonably assure the device's safety and effectiveness. Manufacturers of high-risk Class III devices must go through a rigorous premarket-clearance process in which they provide evidence showing a "reasonable assurance of safety and effectiveness" for the product's intended use. While some lower-risk devices are exempted from premarket review by the FDA, the vast majority are not. Non-exempt, lower-risk devices must show "substantial equivalence" with an already legally marketed device. Thus, even the low-risk devices will be cleared for marketing only if "the device is as safe and effective as a legally marketed device" and "does not raise different questions of safety and effectiveness."

Despite the safety and effectiveness principles underlying the FDA's rules for approval of medical devices, the trial judge in *Ethicon v. Huskey* prohibited the medical device manufacturer from introducing evidence of its compliance with the FDA's premarket notification requirements. The case involved a woman who

experienced complications from the implantation of a transvaginal mesh medical device, specifically a tension-free vaginal tape-obturator (TVT-O). The TVT-O is a mid-urethral sling that uses a heavyweight laser-cut mesh to treat urinary incontinence. The TVT-O was cleared for marketing by the FDA in 2003 under the 510(k) premarket notification and review process, but the manufacturer was precluded from telling the jury that its device had received the FDA's premarket review and clearance, and the trial ultimately resulted in a $3.27 million verdict against the manufacturer.

The trial court ruled that evidence of the FDA's premarket clearance would be of limited value and could potentially confuse jurors. When the manufacturer appealed, the appellate court agreed with the trial court, concluding that such evidence raises a "risk [of] confusing the jury by...causing a battle of the experts over the robustness of the [FDA's] safety examinations" and could result in "wasted time."

These courts' opinions are based partially on a misunderstanding of a prior Supreme Court decision in *Medtronic v. Lohr*. That case focused on whether FDA authorization can *preempt* a design defect claim brought under state law and did not address whether the FDA's review and premarket clearance should be admitted into evidence to defend against, *but not preempt*, a consumer's claims. In *Lohr*, the 510(k) process was described as being only "tangentially" related to safety. But this conclusion ignores that *Lohr* was simply determining whether the 510(k) "requirements" were in conflict with state law "requirements" so as to require preemption of the state design defect claim, not whether those requirements are proof of safety at trial.

If the Supreme Court overturns the lower courts' rulings in *Ethicon v. Huskey*, admission of FDA premarket review and clearance evidence would not provide device manufacturers with an automatic win. FDA clearance decisions are based on varying degrees of safety data, so a plaintiff's attorney would still be permitted to challenge the weight that such evidence should be given. Ultimately, a jury would determine how persuasive the evidence of premarket clearance is based on the facts specific to the individual product's clearance. And that is the point. The jury is the stalwart of the American legal system and should be allowed to consider this evidence so that medical device companies may fully defend themselves. This is especially true in product defect cases where the companies face significant allegations of wrongdoing and potentially huge adverse verdicts.

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