Products Liability Law Daily Wrap Up, SUPREME COURT DOCKET—Recent petitions and cases pending High Court review, (May 31, 2017)

Products Liability Law Daily Wrap Up

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Ethicon, Inc. and its parent company, Johnson & Johnson, have petitioned the U.S. Supreme Court to review a decision by the U.S. Court of Appeals for the Fourth Circuit upholding a $3.27 million jury verdict following a bellwether trial in the multidistrict litigation involving the manufacturers' allegedly defective transvaginal mesh devices. The Fourth Circuit had found that the patient in the case had presented sufficient evidence to support the jury's determination that the mesh device at issue contained a design defect and that the manufacturers failed to carry their burden of showing that they were protected from liability under the unavoidable unsafe product exception to §402A of the Restatement (Second) of Torts [see *Products Liability Law Daily*'s January 27, 2017 analysis]. The appellate court also rejected the manufacturers' claim that a new trial was warranted on the basis that the district court erred in failing to instruct the jury on the unavoidable unsafe product exception and in excluding four pieces of Food and Drug Administration (FDA) evidence. Addressing the evidentiary exclusions, the Fourth Circuit ruled that evidence of the mesh product's compliance with the FDA's section 510(k) "clearance" process, which focuses on the equivalence between the product in question and a product that is marketed legally already while only tangentially examining the safety of the product going through the process, would cause a battle of the experts over the robustness of the 510(k) process and, thus, risked confusing the jury.

The manufacturers' petition focuses on the appellate court's exclusion of evidence of the FDA's 510(k) clearance. They note that the FDA must review medical devices for safety and efficacy before clearing them for marketing and sale; and that under the 510(k) review process applicable to the "Class II" mesh device at issue, the FDA clears the device as safe to market if the agency finds it to be "substantially equivalent" to a device already determined to be safe. The device makers complain that the Fourth Circuit construed *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), incorrectly—"as holding categorically that [the] FDA's 510(k) review process does not encompass meaningful safety review." According to the manufacturers, the Fourth Circuit applied this reading of *Lohr* and held that the FDA's 510(k) clearance of the manufacturers' device was irrelevant to its safety. Consequently, the appellate court affirmed a district court ruling prohibiting the manufacturers from introducing evidence of the FDA's 510(k) clearance to defend against the patient's claims that the device was unsafe. The manufacturers posed the following question to the High Court: "Whether the Fourth Circuit properly applied *Lohr* to hold that safety is irrelevant to FDA's 510(k) clearance of a medical device and that the device's manufacturer therefore may be barred from introducing evidence of 510(k) clearance in defense of a claim that the device is not reasonably safe."

The manufacturers assert that the High Court should grant their petition because the case presents a recurring question of "exceptional importance"—whether a medical device manufacturer can be barred from citing the FDA's 510(k) clearance of the device to defend against claims that the device is unsafe. Certiorari is also warranted, the makers claim, because the Fourth Circuit's decision likely will affect "an extraordinary number of cases"—approximately 60,000 in the pending pelvic mesh MDLs—and likely will affect other similar products going forward. In addition, the makers contend that medical device makers are unable to present a complete defense without providing jurors a truthful account of how the device got to market (*Ethicon, Inc. v. Huskey*, Docket No. 16-1399, filed May 23, 2017).

For details about petitions and cases pending before the U.S. Supreme Court, please consult this list of selected products liability cases awaiting decision during the 2016 term. The list has been updated to reflect this recent order and recent filings of party and amicus briefs. Granted and pending petitions are listed separately, along with a brief summary of the questions raised and status.

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