Products Liability Law Daily Wrap Up, DESIGN AND MANUFACTURING DEFECTS—MEDICAL DEVICES—W.D. La.: Patient's spinal plate claims fall flat, (Mar. 25, 2016)

By Susan Lasser, J.D.

A patient with a degenerative disc disease who had a cervical plate implanted to assist with fusion of his spine, failed in his action against the device manufacturer to establish under the Louisiana Products Liability Act (LPLA) that injuries he alleged were caused by the defective construction and design of the device, a federal district court in Louisiana ruled. Further, he failed to meet his burden under the doctrine of *res ipsa loquitur* to provide an inference of negligence by the manufacturer (*Lyles v. Medtronic, Inc.*, March 23, 2016, James, R.).

Medtronic Sofamor Danek USA, Inc. (MSD), a subsidiary of Medtronic, Inc., manufactures and sells the Atlantis Translational Anterior Cervical Plate System (Atlantis Plate), which the patient had implanted after he was diagnosed with severe progressive myelopathy with stenosis. The product is used as a temporary aid to fusion and to help stabilize the anterior cervical spine during spinal fusions in patients with degenerative disc disease. The product consists of two separate metal components which are joined by a track and runner system to form one plate. Tiny pins within the track and runner system ensure that the plate components remain intact by preventing the runners on the top component of the plate from coming free of the tracks on the bottom component.

Following surgery, the patient complained of increased pain in his upper extremity and neck. He also had difficulty swallowing and reported having fallen twice since discharge, once backwards and hitting his head. X-ray reports indicated that while there was "slight displacement" of the plate, it had not broken and had not become unstable. However, his vertebrae failed to fuse, the patient's pain continued, he lacked feeling and strength in his hands, and he continued to have difficulty walking. A second surgery performed to decompress the patient's spine did not remove the device, but rather included the addition of rods and screws. According to his surgeon, the Atlantis Plate "never failed." However, the patient retained an expert, a neurosurgeon, who opined that the device was installed properly and that there was a "mechanical failure" of the plate. He also said that "it must be *assumed* [the failure] occurred in the period between" implantation and the recovery room x-rays. He admitted in his deposition, though, that he could not identify definitively the cause of the failure, but that he assumed there was failure with the pins keeping the rails in track. He did not offer opinions as to whether a device characteristic contributing to its alleged failure existed when it left MSD's control, as to the device's design, or as to an alternative design.

The patient asserted claims against the manufacturer that the Atlantis Plate was defective in construction or composition and in design. The manufacturer moved for summary judgment, contending that the patient could not establish that (1) the Atlantis Plate contained an unreasonably dangerous characteristic due to its construction or composition or its design; and (2) that an unreasonably dangerous condition existed in the Atlantis Plate at the time it left the manufacturer's control, as required under the LPLA.

Defective design. For the patient to carry his burden of showing that the Atlantis Plate was unreasonably dangerous and defectively designed, he had to show that when the device left the manufacturer's control, there (1) *existed* an alternative design that was capable of preventing the damage, and (2) the likelihood that the design would cause the damage and the gravity of that damage outweighed the burden on the manufacturer to use a different design. However, because the patient admitted that he lacked proof of an alternative design, the court granted summary judgment for the manufacturer on the patient's design defect claim.

Defective construction and the doctrine of *res ipsa loquitor*. The court also granted summary judgment for the manufacturer on the patient's defective construction claim. Under the LPLA, "[a] product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product …." Because the device remained in the patient's spine, it could not be tested. As such, the patient's expert admitted that he could not offer an opinion on the manufacturer's specifications or performance standards for the device or how it materially deviated from those specifications and performance standards. Although the expert assumed

a mechanical failure occurred after surgery, but before the patient left the recovery room, he did not know and could not offer an opinion on what caused the plate to fail. He also could not offer an opinion on whether the mechanical failure occurred before the product left the manufacturer's control. Therefore, the court determined that the patient could not meet his burden of proof based on his expert's testimony.

Res ipsa loquitor. The patient addressed the evidentiary deficiency by arguing that he could rely on the doctrine of *res ipsa loquitor* to show that the construction or composition of the Atlantis Plate used in his surgery was defective at the time it left MSD's control. The doctrine allows for the inference of negligence by defendants, based on circumstantial evidence, when "the facts of the case indicate that the negligence of the defendant is the probable cause of the accident, in the absence of other equally probable explanations offered by credible witnesses."

The patient alleged that the device separated, and, therefore, failed to promote fusion and resulted in an additional surgery. He contended that the doctrine of *res ipsa loquitor* applied because (1) the radiographic images taken shortly after surgery appeared to show the separation of the Atlantis Plate, (2) the experts who reviewed the case did not find an unusual event or that anything went wrong during the surgery, and (3) the Atlantis Plate was allegedly in the manufacturer's control until the moment of surgery. The court noted, too, that the patient continued to assert a malpractice claim against his surgeon.

After its review of the record, the court found the doctrine of *res ipsa loquitor* inapplicable because the patient failed to exclude sufficiently inference of his own responsibility or the responsibility of others in causing his injuries. No one could access the Atlantis Plate, still implanted in the patient's spine, and none of the physicians—neither the patient's surgeon nor his or the manufacturer's experts—could identify the cause of the shifting or misalignment of the plate. In addition, the patient's lawsuit against his surgeon for malpractice asserted that the surgeon improperly installed the device. Thus, the patient failed to exclude evidence that his injuries were the result of the actions of his surgeon, rather than a defect in the Atlantis Plate.

While the patient offered some "possible assumptions," he failed to meet his burden under the doctrine of *res ipsa loquitur* to provide an inference of negligence on the part of MSD. Therefore, he did not establish that the Atlantis Plate, which remained in the patient's cervical spine, was in an unreasonably dangerous condition at the time it left the manufacturer's control.

The case is Civil Action No. 15-0910.

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Companies: Medtronic Sofamor Danek USA Inc.

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