Of Treating Physicians And Manufacturing Defects

Wednesday, July 06, 2011

The new case, Williams v. Mast Biosurgery USA Inc., ___ F.3d ___, 2011 WL 2566426 (11th Cir. June 30, 2011), raises two fascinating issues, but we only offer our opinions about one of them. The facts in Williams are unfortunate, as is true with most of the cases we handle.

The plaintiff, a young lady, was being evaluated for possible infertility. Her treating gynecologist (doctor #1) found an ovarian cyst and drained it. During that procedure, he also found "significant dense adhesions that had resulted from a prior surgery some years before," 2011 WL 2566426, at *1 – surgery that, oddly in our view, was not further described or discussed.

More on that later.

More significant surgery, to remove these adhesions, soon followed. To prevent adhesions from recurring, doctor #1 inserted the medical device in question, a "bioresorbable" (that is, designed to break down and gradually be destroyed by the body's biological processes) barrier manufactured by the defendant.

Anyway, since we're describing a product liability suit, things necessarily went awry. Within a month after this surgery, the plaintiff returned, in bad shape. A colonoscopy (performed by doctor #2 in a different medical specialty) revealed "several stiff, hard and brittle pieces of plastic" perforating the plaintiff's colon. Id. This required a second surgery – by a doctor #3 – which "cleaned out" the material and a significant accompanying infection. Doctor #3 "suspected" the material was from the barrier that had been implanted in the second surgery.

A pathologist (doctor #4), also examined the material. He echoed doctor #3's suspicions, but his testimony turned out to be incomptently based solely on a product label he had been given.

Somehow – the opinion does not describe the circumstances – these plastic pieces were never analyzed "to determine their identity or composition" before they were (we guess, the opinion is less than clear) thrown away. Id.

Oops. It's always a bad idea to lose the product in a product liability case.

This failure to retain the offending pieces was the first problem with the plaintiff's case, which led directly to the second problem – the plaintiff did not retain any experts, instead attempting to make a case solely through the four treating physicians' testimony.

The lack of any expert led to the court's first interesting conundrum – to what extent the plaintiff's treating physicians provided "lay" or "expert" opinion testimony. This distinction is important because expert testimony is subject to Daubert standards. The trial court found that major parts of these physicians' testimony was excludable as incompetent expert testimony. The holes in the plaintiff's case left by those exclusions defeated causation (but not in the way we were expecting), resulting in summary judgment.

The plaintiff appealed.

The distinction between "lay" and "expert" treating physician testimony is important, and there aren't that many appellate cases discussing it in a prescription medical product context (Williams didn't cite any). But this isn't a subject we're opining about ourselves, because depending on how things work out we might find ourselves on either side of this issue in any given case. Sometimes it's the defense that likes the "lay" opinion testimony of the plaintiff's treating physicians – sometimes (as in Williams) it's the plaintiff. So we're not taking sides; just describing the court's resolution of this interesting issue.

As a gross generalization, the "lay opinions" that a treating physician can testify about are those s/he acquired from things observed/done in the course of treating the particular patient. Anything further – resulting from the application of the treating physician's medical knowledge to a broader set of facts – is "expert" testimony that must withstand the rigors of Daubert. As the Eleventh Circuit stated the issue in Williams:

> "Much of the testimony proffered by treating physicians is an account of their experience in the course of providing care to their patients. Often, however, their proffered testimony can go beyond that sphere and purport to provide explanations of scientific and technical information not grounded in their own observations and technical experience. When such a situation presents itself, the trial court must determine whether testimony not grounded in the physician's own experience meets the standard for admission as expert testimony."

2011 WL 2566426, at *4.

There are also procedural differences in how lay opinion testimony, as opposed to expert testimony, is discoverable under the rules. Neither the district court nor the Court of Appeals based their rulings on failure to follow the proper discovery rules. Id. at *3 n.1.

In Williams the plaintiff argued that the testimony of all four physicians (the original gynecologist who drained the cyst and found the adhesions; the implanting surgeon, the explanting surgeon, and the pathologist) should have been admitted in full as "lay" testimony."

The Court of Appeals disagreed, and affirmed the district court (the abuse of discretion review standard undoubtedly helped, too). Critical parts of the treaters' testimony relating to the (now missing and never definitively identified) pieces of plastic crossed the line and were actually expert opinions.

By the way, the plaintiff did not dispute the trial court's Daubert-based expert evidence exclusions on the appeal – so the lay/expert distinction was the whole ball of wax. Williams, 2011 WL 2566426, at *5 n.5.

The court "focus[ed] on the physician statements that the foreign substance removed from [plaintiff's] abdominal cavity was [the product in question]." 2011 WL 2566426, at *4. Indisputably, foreign objects – pieces of plastic – were removed from the plaintiff. That alone, however, did not establish a defect in the defendant's product.

But not for the reason we expected.

Whenever we're in a missing product case, as defense attorneys we go first to product identification, because it's pretty basic that unless the plaintiff can prove that the defendant's product (as opposed to something else) that hurt him/her, that provides an easy, early end to the case. So we were surprised that the earlier surgery was never the subject of any significant discussion. Perhaps those pieces of plastic – never analyzed in any way – were accidentally (or intentionally, but the medical records would probably show that) left over from the first surgery. Something made out of plastic could have broken the first time around.

Those pieces could have been benignly sitting there for years until disturbed by the later surgery to remove the adhesions. A surgeon, not not expecting to find anything of the sort and intent on doing his job, could have moved things around without seeing small pieces of plastic and produced a perforation of the colon .

In any event, Williams did not turn on pure product identification. One piece of admissible lay opinion testimony was doctor #1's statement that he didn't put anything in the patient other than the product. 2011 WL 2566426, at *6. Nobody raised the possibility of leftovers from the prior surgery.

Instead, what doomed the plaintiff's case was a total lack of evidence about whether and how the observed pieces of plastic established a failure of the defendant's product to act in an intended fashion:

"[O]ne other piece of testimony merits our consideration. [Doctor #1] provided the only direct testimony that [the barrier device] had failed to perform as intended and thus was defective. We agree with the district court that such a conclusion requires some knowledge of how [the device] should have performed, a question outside the ken of a lay witness because it must be premised on scientific or other specialized knowledge."

2011 WL 2566426, at *6. Such testimony crossed the line. An opinion about how a bioresorbable product was supposed to perform, how long it ordinarily took to break down, and what the break down products should have been, was "based on a hypothesis, not the experience of treating the patient." Id. at *4.

The procedural takeaway from Williams is that experience with a product generally – beyond the individual plaintiff's treatment – could not be admitted as the lay opinion testimony of a treating physician. Rather, it is expert testimony that was admissible, or not, only subject to the strictures of Daubert.

There was no such Daubert-admissible expert testimony in Williams. As a matter of substantive Georgia law, that meant, because plaintiff could not prove how the product was supposed to perform, there was no evidence that it had failed to perform as expected.

On this second point – what is necessary to establish a manufacturing defect – we have no problem stating that we fully agree with the ruling in Williams. The entire concept of a manufacturing defect is based upon the product not meeting intended performance/specifications, and the plaintiff in Williams, by failing to offer any evidence of proper performance/specifications, flunked out.

In manufacturing defect cases, *res ipsa loquitur* a/k/a "malfunction theory" a/k/a "circumstantial evidence" is always the last refuge of a plaintiff without a case, and that's precisely where the Williams plaintiff sought to hide out – thankfully unsuccessfully. The intended behavior of a bioresorbable product during its first month in the body was not something that a lay juror could understand without the assistance of admissible expert testimony. This situation was not obvious like a "loud rattling noise" in a brand new car. Williams, 2011 WL 2566426, at *6 (distinguishing McDonald v. Mazda Motors, Inc., 603 S.E.2d 456 (Ga. App. 2004)). Nor was it equivalent to pieces of an implantable medical device that reveal a "clear break." 2011 WL 2566426, at *7 (distinguishing Williams v. American Medical Systems, 548 S.E.2d 371 (Ga. App. 2001)).

In short, Williams was hardly an "unremarkable" broken product case:

> "[T]he issue of whether there was a defect concerned a bioresorbable plastic product with which even the treating physicians, let alone the lay jurors, had little to no experience. Under these circumstances, where those who had observed the patient and her condition could not assess accurately what they had observed and its significance, we do not believe that Georgia law would have permitted [plaintiff] to proceed to a jury without testimony about the nature of the product, its properties or its expected functioning when implanted in the human body."

2011 WL 2566426, at *7. The mere fact that some foreign body injured the plaintiff did not establish that this particular product had a manufacturing defect at the time it left the manufacturer's hands. The plaintiff offered no evidence to exclude product mishandling, negligent implantation, contraindicated use, or "other potential causes" of the purported malfunction. Id. at *8.

We would add that there was also no evidence that the foreign bodies even came from the product at all. They could just as well have been artifacts from the prior surgery that – until disturbed by later surgery – had not been causing any trouble.

Bottom line in Williams was that the plaintiff failed to prove any case of manufacturing defect. Beyond that, both sides need to be cognizant of applicable evidentiary limitations whenever relying upon lay opinion testimony of treating physicians. This time the plaintiff stepped in it. Next time, the shoe could be on the other foot.