Screwy

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Bone screws. Yeah, we'd have to say we know a bit about them. And Pennsylvania law – we know something about that as well. Put those two together, and that's why the Pennsylvania Superior Court's recent decision in Wiggins v. Synthes (U.S.A.), ___ A.3d ___, 2011 WL 3524286 (Pa. Super. Aug. 12, 2011), just seems screwy to us. Wiggins affirmed a significant jury verdict against the manufacturer of some bone screws that, when used in the hip joint, broke when there was a non-union (that is, adjacent bones were supposed to heal and knit together, but didn't).

Neither of the Superior Court's two most critical medical device product liability decisions is even cited in the Wiggins opinion. Those are: Creazzo v. Medtronic, Inc., 903 A.2d 24 (Pa. Super. 2006), and Schindler v. Sofamor, Inc., 774 A.2d 765, 771 (Pa. Super. 2001) (yup, Bexis and Michelle did that one).

Creazzo is important because it holds that the Pennsylvania Supreme Court's long-standing restrictions on the causes of action applicable to prescription drugs also apply to prescription medical devices. Specifically:

"[Plaintiffs] challenge the trial court's determination that their strict liability claim is barred by Restatement 2d of Torts section 402A, comment k. . . . [T]he trial court applied this section to the [medical device], citing our Supreme Court's decision in Hahn v. Richter, 543 Pa. 558, 673 A.2d 888, 890-91 (1996), in which the high court adopted comment k, to ***conclude that strict liability could not be applied*** *to prescription drugs where adequate warnings of the drugs' potential risks had been provided. In applying comment k here, the trial court reasoned that given the potential utility of [medical devices], no significant distinction can be drawn between the device and the drug upon which the Supreme Court based its decision in Hahn. The court concluded accordingly that* ***strict liability could not be a basis for liability*** *in this case. [Plaintiffs] contend that the trial court misconstrued Hahn, and that comment k does not apply to medical devices because the comment text does not mention them. They cite no authority, however, for so restrictive an interpretation either of comment k or of Hahn, nor do they provide significant analysis of the language they seek to apply.* ***We find no reason why the same rational applicable to prescription drugs may not be applied to medical devices****."*

903 A.3d 30-31 (various citations omitted) (emphasis added).

So our first issue with Wiggins is why, in the first place, was the Superior Court even applying "strict liability" – and specifically the strict liability "malfunction theory," 2011 WL 3524286, at *2 – in a case involving a prescription medical device (which all implantable bone screws are) governed by Creazzo? Either the Superior Court ignored the controlling (prior Superior Court panel decisions in Pennsylvania are binding on subsequent panels) Creazzo precedent (not altogether implausible), or somebody on the defense side inexplicably decided to let the case go forward in strict liability. Big mistake, if that's what happened.

Then there's the Schindler case, which preceded Creazzo and thus was litigated under strict liability. Schindler rejected the proposition that the "intended use" (which limits the scope of strict liability in Pennsylvania) of internal fixation devices (what bone screws are) was to hold bones together until they grew together ("union"), no matter how long that might be – even though some plaintiff-side expert so opined. As to that point, Schindler held as a matter of law:

*"Determining the product's intended purpose is critical to the court's legal conclusions about whether the product can be deemed defective. . . . **[T]he intended use of a product is a conclusion of law**, to be decided by the trial court. In other words, the trial court is not bound by any party's legal conclusions as to the intended purpose of a product, even if those conclusions are couched as averments of fact or presented as expert evidence. To hold otherwise **would force trial courts (and reviewing courts) to accept unrealistic, generalized, or distorted views of a product's purpose** simply because they are presented as factual evidence."*

774 A.2d at 773 (emphasis added). An inescapable fact of life where metallic implants are concerned is that, when a patient's bones do not fuse together as expected, the metal will suffer fatigue from the body's repeated stress on it and eventually break. The more fatigue, the faster the break. The two most fatigue-prone areas of the body are the lower spine, and the hip – since they not only support the body's full weight, but also anchor the biggest muscles in the body, which allow us to sit up, and to stand upright.

Thus Schindler recognized that the "intended use" of such a device – which determines the permissible scope of strict liability – cannot be to last, hell or high water, until fusion is achieved:

"All parties agree that the [device] is designed to stabilize the spine "until" fusion takes place. It is also undisputed that the [devices] generally do stay in place forever if fusion takes place. Appellants would convert these statements of fact into a conclusion of law that the [device] is defective if it breaks before

fusion takes place. . . . ***The trial court concluded that the [device] was never intended to last indefinitely in the absence of fusion. . . . We see no error of law in this statement of the [device's] intended purpose.*** *[Plaintiffs] presented no evidence that the [device] was intended to stabilize the spine indefinitely in the case of [non-union]. . . . Based on the trial court's appropriately-limited statement of the [device's] purpose. . ., we see no error in the court's conclusion that the product was not unreasonably dangerous as a matter of law. JNOV was therefore appropriate."*

774 A.2d at 774-75 (emphasis added).

So let's compare Schindler's legal conclusions about implanted medical devices "never intended to last indefinitely in the absence of fusion" with what went on in Wiggins. One difference is that the broken hip screws in Wiggins were discarded by the explanting physicians, so they could not be tested. 2011 WL 3524286, at *1. Because of the erroneous (but unchallenged) assertion of strict liability in Wiggins, plaintiffs were allowed to proceed on the strict liability "malfunction theory" where defect (and causation, and defect at sale) were all "inferred" from the purported malfunction – the breaking of the screws. Id. at *2.

Essentially, the court allowed the mere fact of the device breaking to suffice as a defect. There's quite a bit of precedent, which we discussed in our "Them's the Breaks" post, that such reasoning is wrong – for the same reasons recognized in Schindler. But since Wiggins didn't even address it's prior decision in Schindler, it could hardly be expected to respond to precedent from other courts and other states.

Precisely as Schindler held courts shouldn't do, Wiggins treated expert "opinions" that the screws should not break until whenever fusion occurs (if at all) as a matter of "sufficiency of the evidence." Here's what the plaintiffs' experts opined in Wiggins:

- "[W]e see in this particular case is those screws broke **before** [the hip healed] and, therefore, it was ineffective in doing its job." 2011 WL 3524286, at *4.
- When we put an internal device. . ., what we're saying is that – whatever we put in has to hold it together **until** the body takes over the job." Id. at *5.
- "[I]f you, therefore, have a situation where the screws break, both of them break under this, when most of the time you only need one to hold, well, **until** the bone heals, what else can I infer other than that, that there was a defect in the screws?" Id.

- "[Plaintiffs' expert] testified that the screws were supposed to keep the corrected hip in 'position **until** the bone heals.'" Id.
- "[T]he failure was that the bone . . . did not unite **before** the screws broke." Id. at *7.

(Emphasis added throughout).

This testimony is no different to that rejected as a matter of law in Schindler: that medical devices are somehow defective/ineffective/whatever simply because they can break before/don't last "until" fusion occurs. Nonetheless, without even citing the dead on-point (broken medical device; judgment n.o.v.), controlling (see above) Schindler decision, Wiggins concluded that the plaintiff had made out a case. "[T]here was sufficient expert testimony to establish that the surgical screws malfunctioned, and thus, were defective." 2011 WL 3524286, at *5.

That's screwy.

The best we can say about Wiggins is that it's unlikely to be repeated – as long as other defendants assert Creazzo and don't allow other plaintiffs to get away with using strict liability theories in prescription medical device cases in Pennsylvania.