The Dregs - The Ten Worst Drug/Medical Device Decisions of 2011

Thursday, December 22, 2011

Here we go again. At the end of every year, we look back over the past twelve months – the highs and the lows – the thrill of victory and the agony of defeat. We always start with the agony, however, and this year's no exception. Despite our best efforts, our side didn't win everything everywhere. So as we've done for the past four years, we're handing out lumps of coal right before Christmas, specifically the ten worst prescription medical product liability decisions of 2011. These noxious weeds seem to pop up all over. We have federal cases and state cases. We've been burned, of course, by hellhole jurisdictions, but also at least as much (if not necessarily as frequently) in jurisdictions that, until now, hadn't earned that sobriquet.

Like last year, there's still a week and a half left for courts to continue plumbing the depths. There could be a new number one before the end of the year. But, frankly, we want to get this over with before that vulture over there keels over and falls off its dung heap. The last week of the year we reserve for the fun stuff, that is to say our top ten best decisions.

So let's take the plunge – holding our noses all the way. Here are our ten levels of hellhole, our bottom ten worst judicial drug and device decisions of 2011.

1. DiCosolo v. Janssen Pharmaceuticals, Inc., 951 N.E.2d 1238 (Ill. App. 2011). The worst drug/device product liability decision of 2011 earned its dubious distinction by encouraging plaintiffs to lose the product that allegedly caused their injuries. DiCosolo involved a pain killing patch used by a drug addicted (8 different drugs in the bloodstream) decedent whose death was initially ruled a suicide (before the plaintiff's lawyer prevailed on the coroner to alter his findings). The plaintiff had used recalled patches, but the patch found on the decedent's body was tested and unequivocally did not exhibit any sign of the defective condition that prompted the recall. No worries, held DiCosolo, the plaintiff can sue over the patch before that – the so-called "penultimate patch – that conveniently had been thrown away and was unavailable for similar testing. A suspiciously timed affidavit (after a long period of silence) by the financially interested plaintiff just happened to remember seeing the problem that prompted the recall present in the discarded patch. Thus the plaintiff was allowed to bring in the recall to the jury's attention, even though only a minute fraction of the recalled product had the defect. That fraction included the only patch that could be tested (all others having since gone

missing), but despite that test result, DiCosolo let the plaintiff proceed under *res ipsa loquitur*, even though a drug overdose is not a visible malfunction. Nor did DiCosolo trouble itself overly with alternative causes, even though the plaintiff's deficient list had induced the coroner not to test the decedent's blood for overdoses of several other drugs. Goes to the weight, the court held, wrongly, since circumstantial proof only holds together in the absence of such causes. Season this mess with some incompetent fraud on the FDA testimony , and an $18 million verdict was the result. What's the message of this terrible decision? Plaintiffs – throw away your products! You have nothing (in Illinois) to lose but your cases. We made our best Calvin and Hobbes face at this unappetising decision here.

2. Hughes v. Boston Scientific, 631 F.3d 762 (5th Cir. 2011). Hughes allowed an improper private FDCA-violation claim – the defendant's "algorithm" for reporting adverse events allegedly violating some obscure regulation – to masquerade as a tort suit. Why did plaintiff even bother with such a bizarre claim? Because the product was a PMA device and all the usual claims were preempted. This duty-to-report based claim wasn't even plausibly "parallel" to any tort cause of action ever recognized in Mississippi, so Hughes simply "assumed" that the Mississippi Supreme Court (hotbed of judicial liberalism that it is) would recognize the claim. Hughes called it "negligence per se" even though Mississippi doesn't recognize negligence per se where an allegedly-violated statute bars private causes of action. What about Buckman? Hughes bobbled that, too, holding that Riegel (unlike Buckman, an express preemption case) "unequivocally held" that there was an exception for parallel claims (actually, Riegel held only that the plaintiffs waived the whole subject). In one decision Hughes messed up Mississippi common law, express preemption, and implied preemption – a trifecta that warrants a #2 ranking. We vented our frustration at Hughes here.

3. In re Yasmin & Yaz (Drospirenone) Marketing, Sales Practices & Products Liability Litigation, 2011 WL 6302287 (S.D. Ill. Dec. 16, 2011). What happens when one plops a federal MDL in the vicinity of Madison County (yeah, we know, us Philadelphians should talk)? Whatever it is, it's not looking very pretty at the moment, having just yielded the #3 worst decision, and the lowest by a trial court. Before Y/Y, even the worst MDL Daubert decisions at least clipped the wings of the other side's Through-the-Looking-Glass coterie of purported "FDA experts." Not this time. In a spectacular abdication of judicial gatekeeping authority, the Red Queen, the Mad Hatter and the rest get to testify unrestrained – even about purported FDA-related fraud and foreign regulations. Y/Y will overdose the jury with FDA-related fantasy

until the supposed "law" bears only passing resemblance to what the FDA actually enforces. All this in a state – Illinois – where the highest court forbids FDCA-based common-law causes of action (see Martin v. Ortho, 661 N.E.2d 352 356-57 (Ill. 1996)) – something that supposedly matters under Lexecon. We haven't blogged before about this lump of coal in our stockings because it just happened.

4. Forman v. Novartis Pharmaceuticals Corp., 793 F. Supp.2d 598 (E.D.N.Y. 2011). Judicial hubris is bad. Judicial hubris that ignores Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), is worse. Combining the two moves Forman into the #4 slot of our list, ahead of a number of bad appellate cases. As step one, Forman held that New Jersey appellate courts didn't know what they were doing when those courts applied Buckman preemption to the fraud-on-the-FDA exception of New Jersey's punitive damages statute. As step two, Forman held that predicating punitive damages on a finding of fraud on the FDA was okay, despite the unanimous Buckman holding that this was a no-no and the likelihood that punitive damages can exceed compensatory damages, and thus raise even more acutely the adverse consequences that underscored the Buckman result. We kvetched about Forman here.

5. Smith v. Bayer, 131 S. Ct. 2368 (2011). The Supreme Court overturned one of our sentimental favorites, In re Bridgestone/Firestone, Inc. Tires Products Liability Litigation, 333 F. 3d 763 (7th Cir. 2003) (Bexis played a part), and held that, because state class action rules (even if verbatim identical to federal Rule 23) might be interpreted differently, federal denial of class certification wasn't preclusive against the same plaintiff's lawyers seeking to certify an identical class action in some state court. While we don't like plaintiffs being allowed a second bite of the apple – and it's a Supreme Court decision – we only rank Smith #5 because, frankly, the whole problem's become a bit anachronistic. Smith involved a class action that had lain dormant, hiding in the weeds for many years. In the interim, Congress did a rare intelligent thing and passed the Class Action Fairness Act, which moved most of the class actions we care about into federal court. After CAFA uniform (and tougher) class certification standards make the two-bites-at-the-apple issue much less salient than it had been back in the days of Bridgestone/Firestone. We regretted Smith here.

6. Lefaivre v. KV Pharmaceutical Co., 636 F.3d 935 (8th Cir. 2011). Lefaivre allowed what amounted to an improper private FDCA-violation claim to survive as a "breach of implied warranty" action. Supposedly, Levine somehow limits Buckman even though not even Levine

itself claimed to do that. How Lefaivre could give precedence to a two-justice concurrence (about already adjudicated violations) over the 7-justice Buckman majority, which recognized no such exception, is also mystifying. Topping everything off is blatant confusion (if not outright wrong-headedness) – a unique statement that Buckman was somehow a "field preemption" case. All this is worthy of our #6 spot. It certainly didn't help matters that the defendant had entered into a consent decree containing damaging statements. Bad facts (if they even qualify as "facts") clearly helped make bad law. We rolled our eyes at Lefaivre here. At least there's a silver lining, since the case has once again been tossed, this time on compensable loss grounds. See Polk v. KV Pharmaceutical Co., 2011 WL 6257466 (E.D. Mo. Dec. 15, 2011). Redemption anyone?

7. Daniel v. Wyeth Pharmaceuticals, Inc., 15 A.3d 909 (Pa. Super. 2011), is an unfortunate punitive damages (aren't they all?) decision by an appellate court in a large state. Thus it weighs in (and us down) at #7. Daniel allowed punitive damages even though the FDA indisputably had never charged the defendant with any relevant regulatory violation. The basis for punitive damages was apparently failure to test – which doesn't even rate as an independent cause of action in Pennsylvania. Not only that, the plaintiff in Daniel got away with playing "hide the expert," resulting in the jury hearing the recorded opinion of an expert that the expert later testified he had recanted. Beneath all this was a moot footnote (choice of law not being disputed) that the law of the defendant's principal place of business (Pennsylvania has no tort reform whatever concerning punitive damages) should control for punitive damages purposes over the law of the plaintiff's state of residence, a distinct minority position. But in the silver lining department, the Pennsylvania Supreme Court has accepted an appeal concerning the punitive damages aspect of the case. See 2011 WL 6034401 (Pa. Dec. 5, 2011). We blogged about Daniel here and here.

8. Murthy v. Abbott Laboratories, 2011 WL 5416333 (S.D. Tex. Nov. 8, 2011). Without citing any law – and contrary to a lot of law it didn't cite – Murthy announced what amounts to a per se rule that any doctor receiving compensation for participating in a clinical trial involving an investigational drug can't qualify as a learned intermediary under Texas law (although, of course, both side's experts can be paid much more). Since physician compensation in this situation is routine, Murthy amounts to a blanket exception to the learned intermediary rule for all investigational drug cases. Murthy also stretches – á la Hamilton (2010 bottom ten #4) – to carve out a second exception, for DTC advertised drugs, even though there wasn't any DTC

advertising, since the prescriber okayed the information at issue. Except, Hamilton at least was a state court with ostensible authority to change state law. Murthy was a diversity case, without any such pretense, so its adventurous rulings exceeded that court's power under our federal system, not to mention disregarded contrary Fifth Circuit authority. Sigh. At least this decision goes bye-bye if the Texas Supreme Court reverses Hamilton. We called out Murthy's abuse of judicial power here.

9. Slater v. Hoffmann-LaRoche Inc., 771 F. Supp.2d 524 (E.D. Pa. 2011). One of the things that made Madison County such a notorious hellhole back in the day was how the local federal courts collaborated (probably as much for docket control as anything else) in trapping defendants in state court. We're starting to see something similar between the Eastern District of Pennsylvania and the current #1 hellhole, Philadelphia (where we happen to be based). To prevent removal of a case from – guess where – Slater held that a publisher could conceivably be sued for the "inadequate" contents of warnings that it printed. The First Amendment implications are obvious, which is why Pennsylvania courts have rejected similar (non-drug/device) claims against book publishers. But Slater ignores Pennsylvania law and holds, on the basis of one distinguishable (brought against a pharmacy, not a publisher) Massachusetts case that maybe, somehow, Pennsylvania law might impose liability on publishers for substantive errors in what they publish. We published our own views on Slater here.

10. Brewer v. SmithKline Beacham Corp., 774 F. Supp.2d 720 (E.D. Pa., Mar. 24, 2011), Patton v. SmithKline Beecham Corp., 2011 WL 6210724 (E.D. Pa. Dec. 14, 2011), and Maldonado v. SmithKline Beecham Corp., 2011 U.S. Dist. Lexis 142578 (E.D. Pa. Dec. 12, 2011). Maybe we're being too parochial, but here's another example of a federal court bending (or worse) the law to trap defendants in the Philadelphia hellhole. These three decisions run roughshod over several provisions of Delaware corporate law (supported by the Third Circuit's interpretation) and admittedly deviate from the terms of the Supreme Court's "nerve center" jurisdictional test – all because "form" supposedly shouldn't triumph over "substance." Hey, this is corporate law, which is all about form, since corporations are legal fictions to begin with. The result in Brewer, *et al.*, deprives companies with a significant Philly presence of otherwise perfectly legal means of changing residence for purposes of diversity jurisdiction, in effect creating sort of a "product line exception" to corporate law generally. They also create an incentive for companies to up and leave Pennsylvania altogether. We

excoriated Brewer here.

Before we take our much-deserved long, hot shower, for the record we need to mention a couple of truly awful decisions that otherwise would fall through the cracks. Both Stevens v. Novartis Pharmaceuticals Corp., 247 P.3d 244 (Mont. 2010) (covered here) and Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010) (covered here and here), were decided in that ten-day window between our 2010 worst decisions post and the end of 2010. Thus, this terrible twosome isn't really eligible for discredit in 2011, but was timed to avoid censure in 2010. Stevens was adverse in several ways, most notably on the questions of cross-jurisdictional class action tolling and creating a duty to warn treaters not even in the same field as those who prescribed the drug. Bausch – that's easy – it's quite simply the worst Twlqbal decision ever, at least from an appellate court. We couldn't let those two stinkers slouch away unscathed.

We also had to cut a few other candidates: Wright v. Aventis Pastreur, Inc., 14 A.3d 850 (Pa. Super. 2011), was a tour de farce concerning preemption of vaccine design defect claims. Wright added insult to injury, being rushed out while Bruesewitz (see, here) was pending in the United States Supreme Court. Now, with Bruesewitz thoroughly trumping Wright, the latter just wasn't important enough for the top ten. Ditto for Gaeta v. Perrigo Pharmaceuticals Co., 630 F.3d 1225 (9th Cir. 2011), a bad appellate generic preemption case rendered irrelevant by Mensing. See L. Perrigo Co. v. Gaeta, 132 S. Ct. 497 (2011) (summarily vacating bad decision). And just missing the cut (maybe not if we weren't from Philly) is Winter v. Novartis Pharmaceuticals Corp., 2011 WL 5008008 (W.D. Mo. Oct. 20, 2011), which allowed a plaintiff to escape what should have been fatal "I didn't read the warning" prescriber testimony with a Magical Mystery Tour-like argument involving a Dear Doctor letter exquisitely timed to arrive at just the right moment to make some sort of causal difference with the plaintiff's utterly indifferent prescriber.

And thus the torture endeth. Now, only the fun stuff is left. Tune again next week when we celebrate the top ten best drug/device decisions of 2011.