CARLTON FIELDS

2009 Top 10 Pharma Decisions from Florida and the Eleventh Circuit

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1. *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270 (M.D. Fla. 2009).* The first published decision within the Eleventh Circuit applying *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), to preempt claims involving a Class III premarket-approved medical device. Plaintiffs alleged that an implantable pain pump was defective and led to an infection. They made a slew of claims against various defendants, but alleged nothing regarding an actual defect other than the legal standard under Florida law. That was not enough as the court held the strict-liability and negligence claims against the manufacturer defendants and a sales representative preempted because the jury could find a defect even if the defendants complied with the FDA's practices and regulations for manufacture, design, and labeling. The court also disposed of some novel theories of liability against the sales representative related to his role in the implant and revision procedures. Those theories failed because the sales representative had no duty to make medical decisions, did not promote off-label use, did nothing other than properly return explanted hardware to the manufacturer, and informed consent does not apply to non-medical practitioners. 2. A package deal that includes the summary judgments granted in the first two Seroquel MDL test cases in *Haller v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1271 (M.D. Fla. 2009), * and *Guinn v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1239 (M.D. Fla. 2009).* Both cases turned on the insufficiency of plaintiffs' specific causation experts. In *Haller*, neither of plaintiffs' experts survived *Daubert*. One's report was riddled with mistakes and admitted that "[plaintiff] would have developed diabetes whether or not he ever took Seroquel." 598 F. Supp. 2d at 1287. The other expert was unqualified to opine on causation and suffered from many other reliability issues. In *Guinn*, yet another expert admitted that "[plaintiff's] pre-existing health conditions alone could have caused her to develop diabetes." 598 F. Supp. 2d at 1247 (emphasis in original). Better yet, he also admitted that, "to a reasonable degree of medical probability," diabetes would have developed regardless of Seroquel use. *Id.* Florida law applies a well-defined causation standard from *Gooding v. Univ. Hosp. Bldg., Inc.,* 445 So. 2d 1015, 1018 (Fla. 1984), that requires judgment for the defendant "when the matter remains one of pure speculation

or conjecture, or the probabilities are at best evenly balanced." Thus, a tie goes to the defendant. When the plaintiffs' experts fall short of even a tie, the defendant wins and no reasonable jury could decide otherwise. 3. *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586 XXX MB, 2009 WL 4924722 (Fla. Cir. Ct. 15th Jud. Cir. Dec. 21, 2009).* The latest Florida battle in plaintiffs' efforts to expand the anomalous result in *Conte v. Wyeth*, A116707, 2008 WL 4823066 (Cal. Ct. App. Nov. 7, 2008), and hold name-brand manufacturers liable for plaintiffs' use of only a generic medicine. Florida law is nothing like California law, though, and the court granted summary judgment on every claim, including negligence, strict liability, breach of warranties, misrepresentation and fraud, and negligence per se. The case followed the last, similarly favorable Florida case on this specific point, *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. 2d Jud. Cir. Feb. 17, 2006), *aff'd per curiam*, 952 So. 2d 555 (Fla. 1st DCA 2007).* 4. *Goldstein v. Centocor, Inc.*, 310 Fed. Appx. 331 (11th Cir. 2008). Affirming the exclusion of plaintiff's general causation expert and resulting summary judgment in a Remicade case. The expert's opinion was not adequately supported by scientific studies and literature and he did not rely on any epidemiological studies. The four sources that the expert did rely upon – plaintiff's pathology reports, MedWatch case reports, medical textbooks, and article abstracts – did not support his opinion. 5. *Evans v. Matrixx Initiatives, Inc.,* No. 3:07-cv-357-J-34JRK, 2009 WL 2914252 (M.D. Fla. Feb. 18, 2009). Another *Daubert*/causation one-two punch. This time, in a nasal gel case, the plaintiffs' experts were insufficient on general causation because of a laundry list of deficiencies. For starters, they failed to consider the specific zinc compound in the product, were neither epidemiologists nor toxicologists, and lacked knowledge regarding the product. Worse yet, they failed to consider the dose-response relationship, the delivery method, and whether plaintiff "was, or could have been, exposed so as to be injured." *Id.* at *9. To top it off, the experts also failed on specific causation because they relied mainly on temporal proximity and failed to exclude or justify alternative causes. Absent expert testimony on causation, the court granted summary judgment. 6. *Kilpatrick v. Breg, Inc.*, No. 08-10052-CIV, 2009 WL 2058384 (S.D. Fla. June 25, 2009). An arthroscopic surgery and shoulder pain pump case in which the court excluded plaintiff's causation expert and granted summary judgment. Things started to go badly for the expert when he admitted that, despite "an extensive list of articles that [he] purportedly relied upon," he really relied upon only four. *Id.* at *5. Things got worse when the court looked at those four articles. The first (and the only one making a comparative study of humans with pain pumps after arthroscopic shoulder surgery) study lacked any statistical analysis and significance. The second involved only rabbits and ran into the usual problems with using animal studies as proof of general causation in humans. The third involved only two female swimmers and expressly admitted that "the exact cause of the [injury] remains unknown." *Id.* at *7. The fourth was the expert's own editorial that was "to say the least, inadequate as a basis for a scientific judgment about [] general causation." *Id.* That alone would have been enough, but the court proceeded to also note that the expert did not explain background risk and conceded that the scientific literature was inconclusive. The holding on general causation doomed plaintiff's case, but the court rejected specific causation as well, holding that the expert's differential diagnosis, "ultimately rooted in nothing more than temporal relationship," was insufficient. *Id.* at *9-*10. Thus, plaintiff lacked any

expert proof of causation and summary judgment ensued. 7. Another package deal, another MDL, and another *Daubert*/causation combo. Here, it was in the Accutane MDL, first in *In re Accutane Products Liability*, No. 8:04-md-2523-T-30TBM, 2009 WL 2496444 (M.D. Fla. Aug. 11, 2009), and then in *In re Accutane Products Liability*, No. 8:04-md-2523-T-30TBM, 2009 WL 3462395 (M.D. Fla. Oct. 28, 2009). In the first order, plaintiffs were back with the same general causation expert previously excluded two years earlier. He fared no better the second time around because, much like the first time, he drew "overreaching conclusions" from medical literature that suggested only "a 'potential association' or that something is 'perhaps acting as a trigger.'" 2009 WL 2496444 at *1-*2. In the second order, the court entered the obligatory summary judgment against the five cases lacking general causation after the expert's exclusion. 8. *Gomez v. Pfizer, Inc.,* No. 09-22700-CIV, 2009 WL 4908937 (S.D. Fla. Dec. 21, 2009).* This is the most recent pharma decision on pleading under *Iqbal* and *Twombly*. The court dismissed, without prejudice, the negligence and strict-liability claims against two of the manufacturer defendants. To plead negligence, the plaintiffs must plead each defendant's individualized duty, including its relationship to the product, and the specific breach of that duty. To plead strict liability, the plaintiffs must plead each defendant's role in the design and manufacture of the specific product, specify whether their claim is for design, manufacture, and/or failure to warn, and plead facts suggesting what was actually defective about the product under each of those theories. *Gomez* follows a line of pharma decisions within the Eleventh Circuit that clarify what plaintiffs must plead under *Iqbal* and *Twombly*. *See Bailey v. Janssen Pharmaceutica, Inc.,* 288 Fed. Appx. 597, 607-09 (11th Cir. 2008) (allowing claims for strict-liability design and manufacturing defects to proceed when plaintiff made specific allegations and identified specific facts showing how the product was defective under those theories, but dismissing the strict-liability failure-to-warn claim when plaintiff failed to plead how and why the warning was inadequate, and dismissing the negligence claims when plaintiff failed to plead the source of each individual defendant's duty and breach); *Wolicki-Gables v. Arrow Int'l, Inc.*, No. 8:08-CV-151-T-17MSS, 2008 WL 2773721, at *2 (M.D. Fla. June 17, 2008) (dismissing all claims because plaintiff must do more than plead only "broad allegations of every theory of recovery against each separate [d]efendant.").* 9. *Hoffmann-La Roche Inc. v. Mason*, No. 1D08-2032, 2009 WL 3430190 (Fla. 1st DCA Oct. 27, 2009). A straightforward application of the "would have prescribed anyway" form of the learned intermediary doctrine to reverse a jury verdict in an Accutane case. A prescribing physician understood the risks and "made an informed decision to prescribe the drug for [plaintiff] despite the risk." *Id.* at *2. More pointedly, that prescriber "testified that he would still be willing to prescribe Accutane to his patients even if there was evidence showing that it could cause IBD in rare cases" and "also testified that even if the warning label contained all of the information suggested by [plaintiff's] expert, he would still have prescribed the medication for [plaintiff]." *Id.* The court did not further analyze another prescribing physician who "admitted that he did not consult a prescribing reference manual before prescribing the drug for [plaintiff]." *Id.* at *1. 10. *Devore v. Howmedica Osteonics Corp.*, No. 3:09-cv-690-J-32HTS, 2009 WL 3110814 (M.D. Fla. Sept. 28, 2009).* A textbook application of two fundamental removal standards, the burden-shifting test for fraudulent joinder under *Legg v. Wyeth*, 428 F.3d 1317 (11th Cir. 2005), and the necessary showing and timing

for removal under *Lowery v. Alabama Power Co.,* 483 F.3d 1184 (11th Cir. 2007). On fraudulent joinder, defendants properly rebutted by affidavit and other documents each of the claims against the non-diverse device distributor. When plaintiff failed to dispute that evidence and show the distributor's connection to the specific device implanted in plaintiff, then the distributor was fraudulently joined. On the *Lowery* standard, defendants correctly treated the initial complaint as non-removable and later removed based upon receipt of plaintiff's written discovery responses, supplemented by a pre-suit demand letter. Of note, the court rejected plaintiff's attempt to neither admit nor deny the basis for jurisdiction and held that it would not "countenance such gamesmanship." 2009 WL 3110814 at *7 n.13. **Finalists:** This quartet of non-Florida cases applying Florida law missed the Top 10 but qualify as finalists: 1. *Hall v. Bristol-Myers Squibb Co.*, No. 06-5203 (FLW), 2009 U.S. Dist. LEXIS 121057 (D.N.J. Dec. 30, 2009). Dismissing, without prejudice, Florida negligent-misrepresentation and consumer-fraud claims because plaintiffs failed to plead causation and reliance in a plaintiff-specific fashion by failing to identify "a single instance in which they, themselves, or any of their prescribing doctors received a misrepresentation of fact on which they relied upon in either taking or prescribing any of the subject drugs." *Id.* at *30. 2. *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-md-1760, 2009 WL 2497229 (M.D. Tenn. Aug. 13, 2009). Summary judgment granted because the Florida government-rules statute, section 768.1256(1), provided a presumption of no defect for FDA-approved labeling and plaintiff did not rebut that presumption. 3. *Williams v. Cyberonics, Inc.*, No. 06-5361, 2009 WL 2914414 (E.D. Pa. Sept. 10, 2009). Florida law manufacturing-defect claims against a PMA device preempted. Plaintiff could not rely upon an inference of a defect under the *Cassisi* doctrine (occasionally employed to allow a plaintiff to survive summary judgment absent proof of a defect if the product malfunctioned during normal operation) to prove a "parallel" claim. 4. *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2009 WL 2004540 (E.D.N.Y. July 1, 2009). Summary judgment granted under Florida law because a different warning would not have changed the prescriber's conduct.

* Carlton Fields participated as defense counsel in these cases.

Authored By

David J. Walz

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