Medical Device Preemption Developments

Wednesday, January 11, 2012

Boring title, but accurate. Here's the latest.

First, Medtronic won another one the other day. Duggan v. Medtronic, Inc., ___ F. Supp.2d ___, 2012 WL 45503 (D. Mass. Jan. 10, 2012), involved an insulin delivery system. It had a number of components, including the pump, which physically moved the insulin from where it's stored into the body. Plaintiffs alleged that the pump malfunctioned and caused undisclosed injuries.

The insulin system was a PMA device, so the defendants moved for summary judgment on grounds of preemption. Plaintiffs targeted the pump, rather than any other aspect of the system, because the pump had originally been §510k cleared (unpreempted under Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)) – by itself – in 2004. The insulin delivery system predated the pump, and was PMA approved. By PMA supplement in 2006, the FDA approved incorporation of the pump into the system. The plaintiff was prescribed that system. Duggan, 2012 WL 45503, at *3-4.

Plaintiffs' primary argument for avoiding preemption was that the components in the system should be parsed, the 2006 PMA supplement ignored, and the pump treated as a "mere" §510k device. They got nowhere. The same argument had been made, and rejected, in other device system litigation (mostly knee implants, if we recall):

> "Many courts have held that once premarket approval is granted, all claims relating to all components of the device are preempted. This analysis applies even where a component of a PMA-approved device had previously been approved through the § 510(k) process."

Id. at *4 (citations omitted).

Plaintiffs then tried component part argument 2.0, claiming that the data in the defendant's supplement was insufficient to support PMA approval of the pump. Id. at *5. The opinion doesn't detail the basis of that argument, but we assume that some malleable FDA "expert" was involved. The court refused to allow PMA preemption turn on a litigant's after-the-fact

deconstruction of the approval submission. What the FDA decided, not what a litigant claimed that the FDA should have decided, controlled:

"[T]he sufficiency of the data submitted to the FDA with respect to the safety and efficacy of a device does not govern the scope of the premarket approval. Whether a product is FDA-approved is determined by the language in the approval letter, not by the application documents submitted to it for review. The FDA, not litigants, is entrusted with the responsibility to police the sufficiency of the evidence to support a PMA approval."

Duggan, 2012 WL 45503, at *5 (citing our old pal, Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001)). We view this holding as the most important takeaway from Duggan.

Interestingly, plaintiffs also tried to intervene with the FDA itself, attempting to depose Agency personnel and filing an FDA citizen's petition challenging the scope of the PMA. 2012 WL 45503, at *3. Both moves backfired. It's really difficult to depose government personnel when the government doesn't want it. E.g., United States ex rel. Touhy v. Regan, 340 U.S. 462 (1951). That goes double for the FDA in the First Circuit. See Giza v. Secretary of HEW, 628 F.2d 748 (1st Cir. 1980). Oops. Duggan, 2012 WL 45503, at *5 (plaintiffs forced to drop subpoena). On top of that, the FDA denied the petition, reaffirming that the PMA covered the entire system. Really oops. Id. ("[t]o the extent there was any ambiguity about the scope of the approval letter, this rejection of the Citizen Petition is the cherry on the icing"). Observing that plaintiffs had thusly shot themselves in the foot, the court granted summary judgment. Id.

Second, Boston Scientific won a preemption motion in a rather unusual case in Erickson v. Boston Scientific Corp., No. SACV 10-698 AG (ANx), slip op. (C.D. Cal. Dec. 12, 2011). We're only just finding out about it, though. The unusual nature of the case is the general attack on the life expectancy of several of the defendant's products (pacemakers powered by batteries). The plaintiff claimed that he had been told that four different pacemakers "would last ten years" but that none of them (except the last, which hadn't been implanted very long) came close to that lifespan. Slip op. at 2.

Erickson was dismissed via judgment on the pleadings. So, initially, it is a valuable judicial notice decision, as the court took judicial notice of the FDA approvals of all four pacemakers (six total FDA documents) – a PMA, two PMA supplements, and several supplemental product development protocols ("PDPs"). Slip op. at 3-4. Judicial notice, of course, allows for

dismissal on the pleadings, thereby saving considerable discovery expense and reducing the nuisance value of plainly preempted litigation.

Erickson held that both of these regulatory avenues – the PMA supplements and supplemental PDPs – were equivalent to pre-market approval, and thus preemption under Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), barred the action. Slip op. at 7. The decision discussed supplemental PDPs at some length:

"Some of Defendants' pacemakers were not subject to the FDA's PMA process, but were instead approved through the FDA's supplemental Product Development Protocol ("PDP"). In Reigel, the Supreme Court stated that an application for supplemental premarket approval is "evaluated under largely the same criteria as an initial application." Riegel v. Medtronic, Inc., 552 U.S. 312, 319. Courts have interpreted Reigel to mean that preemption applies equally to both the PMA and PDP processes."

Slip op. at 8 (other citations omitted). We've seen supplemental PMA and PDP preemption decisions before (see our device preemption scorecard for details), but Erickson is the first case we can recall specifically discussing a supplement to a PDP in the context of preemption. That's probably the most important takeaway from Erickson.

In Erickson the plaintiff also trotted out the "parallel violation" exception. Slip op. at 9-10. The defendant made mincemeat of it – aided significantly by the plaintiff's failure to plead anything resembling an adequate parallel claim. Plaintiff did not allege what was violated or how that related to his claim. Id. at 9-10. That didn't cut it:

"[A] plaintiff cannot simply incant the magic words "[defendant] violated FDA regulations" in order to avoid preemption. Rather, a plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue, or identify specific PMA requirements that have been violated."

Slip op. at 9 (citations and quotation marks omitted).

The only thing specific that the plaintiff in Erickson alleged was that some of the pacemakers had been recalled. A bare allegation of a recall, however, wasn't nearly enough. First, "[m]any courts have recognized that product recalls do not create a presumption that FDA requirements have been violated." Slip op. at 10 (citations omitted). Second, recalls do not amount to withdrawal of approval. Id. Third, the recall wasn't even relevant, since there was

no allegation "that the recall was prompted by defects relating to the pacemakers' longevity." Id.

The treatment of the recall is a second very usable takeaway from Erickson. Finally, for the record, Erickson also dismissed fraud claims as insufficiently pleaded, slip op. at 10-11, and throws out several of the claims (the older pacemakers) under the statute of limitations. Id. at 13-15.