Two New PMA Preemption Cases

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You all know we love preemption. So, when two favorable medical device preemption decisions are entered on the same day, well that's a two-fer we can't wait to blog about. In both cases, plaintiffs tried to plead and argue their way around PMA preemption – unsuccessfully. Here is the spin plaintiffs tried and why it didn't work.

Bentzley v. Medtronic, Inc., 2011 U.S. Dist. Lexis 136570 (E.D. Pa. Nov. 28, 2011): This one involves an insulin and glucose monitoring system. The system includes a sensor/transmitter and a pump that work together to monitor the patient's glucose levels and administer insulin automatically and continuously. Id. at *2. Plaintiff alleged that his system malfunctioned and failed to administer the correct dosage of insulin and the reason for the malfunction was that it was exposed to high-strength electromagnetic fields during his employment. Id. at *7-8. This is a known risk with this particular system and one that prompted a Class 2 Recall a year before the system was implanted in plaintiff, including the addition of warning information in the systems shipped to new customers. Id.

The system received pre-market approval and therefore, plaintiff was faced with trying to get around Riegel v. Medtronic, Inc., 522 U.S. 312 (2008). His argument was that to consider the preemption issue, the court needed to break down the "system" into its component parts. Wrong. Plaintiff argued that the pump "is separate and apart from the insulin infusion system and did not gain approval through the PMA process." Bentzley, 2011 U.S. Dist Lexis 136570, at *16. He tried to suggest that the pump had received approval through the §510(k) process and therefore fit under the Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) rationale.

The court found that plaintiff had neither the requisite factual nor legal support for his argument. In fact, the court cited to the FDA's recent rejection of a Citizen Petition requesting that the FDA clarify that their PMA letter for the system did not extend to the pump itself. Bentzley, at *15. The FDA's response was that the system was the entire system – the sensor and the pump. The pump had been modified and combined with the sensor to create the system.

"Accordingly, FDA approved the PMA supplement for the . . . System, including both the . . . pump and the . . . sensor, on April 7, 2006. . . . [T]he approval letter, as issued, applies to the . . . System as a whole."

Id. at *17 (quotation marks omitted). Seems clear enough to us. The court thought so too.

As for lacking legal support, the court includes a nice string of citations to the cases (involving knee implants) that have rejected the component-part argument. See id. at *18-19. So, the court went on to grant summary judgment to defendant on plaintiff's strict liability and negligence design defect claims (manufacturing and design defect claims "are state requirements that are preempted by MDA because of their potential conflict with FDA labeling, design, and manufacturing requirements, id. at *22) and breach of implied warranty claims ("[i]mplied warranties in Pennsylvania are centered around the accepted standards of design and manufacture" which differ from the "federal requirements relating to design and manufacture, id. at *25-26) as preempted. See id. at *21-26.

The concordance of Bentzley with the knee implant cases is a lesson that we never tire of pointing out – the success of one manufacturer with one product will redound to the benefit of other defendants with other products. That's what this blog is all about.

The Bentzley court gave the plaintiff something of a pass on his manufacturing defect and failure to warn claims supposing that plaintiff intended to allege non-preempted parallel claims premised on violations of FDA manufacturing and warning requirements. Id. at *24. But that Annie Oakley didn't get the plaintiff very far, because he had no evidence to raise a genuine issue of material fact that the system departed from FDA manufacturing standards, id. at *30, or that the system was not accompanied by the FDA-required warnings. Id. at *42-43. So, both those claims were likewise dismissed. To be complete, the court ruled plaintiff's express warranty claim was not preempted because express warranties "do not independently arise by operation of state law" and therefore "[do] not involve a state requirement and [are] not preempted by MDA." Id. at *26-27. Defendant's summary judgment motion, however, did not address the merits of plaintiff's express warranty claims beyond preemption – so whether they are viable remains to be seen.

Bush v. Thoratec Corporation, 2011 U.S. Dist. Lexis 136838 (E.D. La. Nov. 28, 2011). This one involves a heart pump that allegedly stopped working and supposedly caused plaintiff's cardiac arrest and subsequent death. Id. at *2. The heart pump is also a Class III

medical device that received premarket approval and is therefore subject to Riegel preemption. Id. at *6. For purposes of plaintiff's arguments, it is important to note that the heart pump at question was subject to a voluntary recall.

Plaintiff argued that one of her claims was not preempted – that defendant failed to notify her of issues with the heart pump – a/k/a fraudulent concealment. Id. at *12. Louisiana law, however, does not recognize a claim for fraudulent concealment against a product manufacturer. So, plaintiff spun her claim accordingly.

"[Defendant] did not completely notify the FDA of the nature of [heart pump] malfunctions, pursuant to FDA regulations. . . Plaintiff theorizes that if [defendant] had fully informed the FDA, the FDA would have issued a Class I recall rather than a Class II recall and had the FDA classified [the] recall as Class 1, it would have likely imposed more stringent notice requirements, and expanded the class of recipients of the notice, including end users like [plaintiff]."

Id. at *13 (quotation marks and citations omitted). That's a lot of ifs and maybes. Plaintiff asserts two legal arguments why this claim is not preempted. One is a well-worn legal theory – fraud-on-the-FDA – and one more novel approach – a recall exception.

We'll start with the purported recall exception. We've known about that little savings clause in 21 U.S.C. §360h(d) since Bone Screw days. It didn't help the plaintiffs then, and it isn't helping them now. In Bush, the plaintiff argued that her claims weren't preempted because §360h(d) "permits state court remedies for claims relating to compliance with recall notifications issued by the Secretary of Health and Human Services." Id. at *9. The court's response: "Plaintiff has not cited any authority for the proposition that § 360h(d) giveth back what § 360k taketh away." Id. at *11 (also citing Riegel, 552 U.S. at 325 n.4 (§360h(d) "could not possibly mean that all state-law claims are not pre-empted, since that would deprive the MDA pre-emption clause of all content.")).

In addition to no legal support, plaintiff had no factual support for her theory either because the recall at issue was voluntary and did not involve an order issued pursuant to §360h(d) – the only context to which the savings clause may apply. Id. To top it all off the court called the plaintiff to task for misrepresenting §360h(d) as applying to the entire Act, instead of merely recalls under that section. Id.

With no recall exception, plaintiff tried fraud-on-the-FDA. We won't re-hash the whole fraud-on-the-FDA argument but rather point you to our prior posts on the subject and specifically our prior discussion of Hughes v. Boston Scientific Corp., 631 F.3d 762, 768 (5th Cir. 2011). Plaintiff here apparently attempted to use Hughes to by-pass Buckman preemption by arguing that her claim was a "viable parallel state-law claim predicated on violation of FDA regulations." Id. at *12. The court didn't buy it:

"Plaintiff's claim of fraudulent concealment depend[s] on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue, as in Buckman. . . .Moreover, Plaintiff is arguing that [defendant] breached disclosure duties owed to the FDA, not that [defendant] breached a disclosure duty owed to Plaintiff by failing to comply with FDA regulations. Under Buckman, such a claim is preempted."

Bush, 2011 U.S. Dist. Lexis 136838, at *15-16. The court, however, was inclined to give the plaintiff a chance to amend her complaint to state a claim more like Hughes (a state law duty to warn based on the manufacturer's alleged breach of applicable federal regulations) and less like Buckman. So, this plaintiff may take another stab at trying to dodge preemption, but for now we put these two cases in the win column.