Product Development Protocol? Preempted.

Tuesday, September 06, 2011

Just a note about Malbroux v. Jancuska, 2011 U.S. Dist. Lexis 96590 (W.D. La. Aug. 29, 2011), an otherwise forgettable opinion throwing out medical device claims on the basis of preemption under Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). Malbroux is forgettable: (1) because it's a pretty much routine application of Riegel to allegations that don't even attempt to make any sort of violation claims, and (2) because the plaintiff was pro se, so he probably didn't know he needed to in any event.

What's interesting to us is the nature of the device as to which preemption was found. Rather than the usual pre-market approval, the device in Malbroux (an "Inflatable Penile Prosthesis" according to the complaint), was being marketed according to a "product development protocol." The court found no material difference between that and PMA, and dismissed on express preemption grounds:

"This preemption clause operates to safeguard the Food and Drug Administration's ("FDA") comprehensive analysis concerning both PMA (Premarket Approval process)-approved and PDP (Product Development Protocol process)-completed devices from modification or interference through the varying tort law principles of the fifty states."

Malbroux, 2011 U.S. Dist. Lexis 96590, at *5. Later on, the court reiterates the point:

"PDP completion is equivalent to PMA approval, thus, if a device is PMA-approved or has received a declaration of PDP completion, then the first prong of the preemption analysis is satisfied . . . . [The device] that is the subject of this lawsuit received a declaration of PDP completion. The conditions of PDP approval governs [the] design, manufacturing and labeling of the device. Therefore, through the PDP process, the FDA has established federal "requirements" that apply specifically to the Penile Prosthesis."

Id. at *6-7.

Thus we'll add Malbroux to our still small (but growing) pile of product development protocol preemption decisions. See Nimtz v. Cepin, 2011 WL 831182, at *3-4 (S.D. Cal. March 3, 2011); Cowen v. American Medical Systems, 2006 WL 3542704, at *1-2 (E.D. Mich. Dec. 7,

2006); Betterton v. Evans, 351 F. Supp.2d 529, 535-36 (N.D. Miss. 2004); Clement v. Kaiser Foundation Health Plan, Inc., 2004 WL 3049753, at *4-5 (C.D. Cal. Dec. 17, 2004).