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PRODUCST LIABILITY

Federal Preemption Stops Common Law Products Liability Claims for Pre-Market Approved Medical Devices

by Dylan O. Malagrino
Column Editor: James R. Lance

*Dylan Malagrino is an associate at Kirby Noonan Lance & Hoge LLP, where he practices complex business law, class-action litigation and professional negligence law. He received his Juris Doctor from the University of San Diego School of Law where he was Editor-in-Chief of the San Diego International Law Journal. Mr. Malagrino has completed the course work for a Ph.D. in Law, and has been awarded an M.Sc. in Law and Anthropology from the London School of Economics and Political Science. He is a certified world economist from the Maxwell School of Citizenship and Public Affairs. He may be reached by email at: **dmalagrino@knlh.com**.*

Recent cases have shown that federal preemption is a very powerful defense for a pharmaceutical or medical-device manufacturer to use in common law products liability litigation. A January 2008 decision by the California Court of Appeals for the Second Appellate District (Seventh Division) found that the rigorous federal pre-market approval process results in federal preemption of common law tort claims for medical devices. In doing so, this court made it nearly impossible for a plaintiff to bring a state common law products liability action against a medical device manufacturer.

An analysis of the policy arguments regarding federal preemption of state statutes is beyond the scope of this article. Instead, this article merely discusses recent developments in the California case law regarding whether common law tort claims based on medical devices are preempted by federal statute.

California Law re Federal Preemption of State Claims

Many cases recognize a broad federal preemption in product liability cases for pre-market approved ("PMA") medical devices. Recently, there have been several California cases interpreting the interplay between such common law state tort litigation and the possible federal preemption of the claims. See, *Steele v. Collagen Corp.* (3d Dist. 1997) 54 Cal. App. 4th 1474; *Scott v. CIBA Vision Corp.* (1995) 38 Cal.App.4th 307; *Armstrong v. Optical Radiation Corp.* (1996) 50 Cal. App. 4th 5801; *Blanco v. Baxter Healthcare Corp.*, G038255 (Cal. App. 4th Dist. Jan. 11, 2008). In *Armstrong v. Optical Radiation Corp., supra*, Division One of the Second Appellate District held there was no preemption of a plaintiff's state law claims for negligence, strict liability, and breach of warranty arising out of the use of a Class III medical device that had completed the PMA process because there is an exception to preemption in the FDA regulations for state or local requirements of *general applicability* when the purpose of the requirement relates either to other products in addition to medical devices or to unfair trade practices in which the requirements are not limited to medical devices. 21 C.F.R. §808.1(d)(1).

Citing the U.S. Supreme Court's decision in *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, the *Armstrong* court held that the state law requirements imposed by negligence, strict liability, or breach of warranty claims fell within this exemption – they were not specifically developed with respect to medical devices; rather, they are requirements of general applicability in which the

purpose of the requirement relates to other products in addition to medical devices. Therefore, the state requirements in such causes of action escape preemption because their generality leaves them outside the category of requirements that the MDA envisioned with respect to specific devices.

Jessen v. Mentor Corp.

On January 16, 2008, in *Jessen v. Mentor Corp.*, 2008 *Daily Journal D.A.R.* 808, the California Court of Appeals for the Second Appellate District (Seventh Division) upheld federal preemption of state products liability claims for a Class III PMA medical device, affirming the judgment of the trial court that recovery was barred based on the doctrine of federal preemption and preemption by the Medical Device Amendments of 1976 (21 U.S.C. § 360c *et seq*.) ("MDA") to the Food, Drug and Cosmetic Act.

At issue in *Jessen v. Mentor Corp., supra*, was a prosthetic testicle. Plaintiff David Jessen had a cancerous testicle removed and replaced with a testicular prosthesis designed, manufactured, labeled, and sold by Mentor Corporation as the "Mentor Saline-Filled Testicular Prosthesis". The prosthesis, which had been shipped unfilled, was not filled with saline prior to its implantation as was directed in the enclosed instructions. The prosthesis subsequently became deformed, causing Jessen pain, and ultimately it had to be replaced.

Jessen sued Mentor alleging causes of action for strict liability, negligence, and breach of warranty. The court noted that the prosthesis was named the "Mentor Saline-Filled Testicular Prosthesis"; however, it arrived unfilled and needed to be filled with saline prior to implantation, and there was no significant difference in appearance or weight between an unfilled and filled implant. Jessen's argument was that Mentor failed to include a warning on the outer packaging of the prosthesis that it must be filled prior to implantation. The trial court granted Mentor's motion for summary judgment on the ground that Jessen's state law claims were preempted by federal law. Jessen appealed.

The court focused its analysis on Jessen's argument that his state tort claims were not preempted by federal law because of a recognized exception to the MDA preemption. In its decision to affirm summary judgment in Mentor's favor, the court upheld the application of preemption to this Class III device, largely because of the rigorous PMA-review process required by the MDA.

The *Jessen* court explained that the MDA was enacted "to provide for the safety and effectiveness of medical devices intended for human use." *Medtronic, Inc. v. Lohr, supra,* 518 U.S. 470, 474. The MDA classifies medical devices into three categories based on the risk they pose to the public. Class I devices, like tongue depressors, pose little or no public health threat; Class II devices, such as an oxygen mask, involve a higher degree of risk. Class III medical devices pose the greatest risk; thus, they are subjected to the most stringent controls. *Scott v. CIBA Vision Corp.* (1995) 38 Cal. App. 4th 307, 315. Examples of Class III devices include pacemakers, silicone inflatable breast prostheses, and "solid or gel-filled silicone rubber prosthes[es] that [are] implanted surgically to resemble a testicle." See, *Goldsmith v. Mentor Corp.* (D. N.H. 1995) 913 F.Supp. 56, 59. In *Goldsmith*, there was no triable issue of fact whether the "Mentor Large Testicular Prosthesis" was Class III medical device.

The *Jessen* court emphasized that before a new Class III device is introduced into the market, a manufacturer must provide the Food and Drug Administration (FDA) with "reasonable assurance" that the device is both safe and effective. This "reasonable assurance" requires what is known as FDA pre-market approval (PMA). The *Jessen* court stressed that obtaining PMA is a rigorous process and noted that a product's labeling is within the purview of this PMA process.

Further, the MDA includes an express preemption provision, prohibiting states from imposing any requirement that is different from, or in addition to, the rigorous federal requirements related to the safety or effectiveness of PMA medical devices. Accordingly, a majority of California and federal courts have concluded all state common law claims relating to the safety or effectiveness of a PMA medial device, other than those based on a violation of FDA requirements, are preempted.

The *Jessen* court declined to follow the earlier Second Appellate District (First Division) decision in *Armstrong v. Optical Radiation Corp.*, *supra*, which allowed for a state tort claim for products liability based on a Class III medical device. Strongly disagreeing with the analysis of the *Armstrong* court, the *Jessen* court explained that in *Medtronic* , *supra*, a majority of the U.S. Supreme Court found a "requirement" within the meaning of the MDA's preemption provision could encompass state common law actions, but simply found that none of the plaintiff's common law tort claims were preempted because the device at issue had *not* gone through the FDA's rigorous PMA process. Instead, it had been marketed under the alternative "substantially equivalent" procedure, which did not establish a federal "requirement" specifically applicable to the particular device in question within the meaning of the MDA.

In Armstrong's action and in Jessen's action, both of the devices had gone through the PMA process. But, the *Armstrong* court did not find preemption, whereas the *Jessen* court did.

Contrary to plaintiff Jessen's contention, the *Jessen* court found it was not bound by the *Armstrong* decision out of Division One of the same Second Appellate District. The *Jessen* court claimed there was no "horizontal stare decisis" within the California courts of appeal. One district or division may refuse to follow a prior decision of a different district or division for the same reasons that federal courts of appeal of the various circuits make independent decisions.

The *Jessen* court recognized that neither the U.S. Supreme Court nor the California Supreme Court has ruled whether the general requirements imposed on a PMA medical device by state common law actions are encompassed within the meaning of the MDA's preemption provision. It then concluded that state common law tort actions relating to the safety or effectiveness of PMA medical devices do have requirements that are different from, or in addition to, the federal requirements, and thus are preempted by the MDA.

The *Jessen* court cited to the majority opinion in *Medtronic*, where it emphasized that federal preemption was triggered by state imposition of any "requirement" that differs from "federal requirements relating to the safety or effectiveness of medical devices intended for human use." Justice Breyer wrote that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." Likewise, Justice O'Connor in her concurring opinion in *Medtronic* agreed that if the MDA's language is given its ordinary meaning, it clearly preempts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the Food, Drug and Cosmetics Act just as it would preempt a state statute or regulation that had that effect.

As such, the *Jessen* court found that *Armstrong* applied *Medtronic* incorrectly because it essentially ignored Justice Breyer's statement in *Medtronic* that common law standards of care and behavior impose specific requirements, even though the general duty may not. Consequently, plaintiff Jessen's state law claims were preempted unless he could demonstrate a triable issue of fact that Mentor failed to adhere to federal regulatory standards, which he could not. Therefore, because the prosthetic testicle in this case had gone through the rigorous PMA process, Jessen's common law claims were subject to federal preemption.