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Preemption: Coming To A Court Near You In 2009

Law360, New York (January 22, 2009) -- The United States Supreme Court's ("USSC") recent and imminent decisions concerning federal preemption will likely have a noticeable impact in 2009 on pharmaceutical and medical device litigation.

Within the past month, a federal district court coordinating a major multidistrict litigation terminated it entirely by dismissing all claims with prejudice based upon the USSC's Riegel v. Medtronic Inc., 128 S. Ct. 999 (U.S. 2008) decision. In re Medtronic Inc. Sprint Fidelis Leads Products Liability Litigation MDL No. 08-1905 (D. Minn. 2008) ("Sprint Fidelis").

Furthermore, in early October, the USSC heard oral argument in Wyeth v. Levine, a case which has the potential to greatly impact the viability of failure-to-warn claims involving pharmaceuticals.

Finally, the USSC recently rejected federal preemption in the arena of tobacco products in Altria Group Inc. v. Good. In light of Levine, it is worth considering what, if anything, Good portends for federal preemption in the pharmaceutical arena.

Therefore, a closer look at these cases is necessary to understand their potential impact on pending pharmaceutical and medical device litigation.

Riegel's Impact: Termination Of An MDL

In Riegel, the plaintiff sued the manufacturer of a balloon catheter used in his angioplasty after the catheter ruptured. The FDA approved the catheter at issue in 1994 under the pre-market approval ("PMA") provisions of the Medical Device Amendments of 1976 ("MDA") of the U.S Food, Drug & Cosmetic Act ("FDCA").

Furthermore, the FDA approved changes to the catheter's label in 1995 and 1996. The plaintiff's

suit alleged claims of defect design, defective manufacture and failure to warn.

The district court dismissed the claims, holding that the express pre-emption provision of the MDA pre-empted the plaintiffs' claims. On appeal, the USSC affirmed the dismissal.

The USSC noted that the MDA contained an express preemption provision that preempted only state requirements "different from, or in addition to, any requirement applicable ... to the device" under federal law.

Tracking the language of the provision, the USSC first noted that the PMA provisions of the MDA imposed "requirements" under the FDCA because the device must be made with almost no deviations from the specifications in the PMA application.

Furthermore, the USSC opined that permitting the plaintiff's claims to proceed would impose requirements "different from, or in addition to" the requirements imposed during the PMA process.

Since the catheter at issue obtained PMA by the FDA and the plaintiff's claims, if successful, would impose state requirements that differed from or added to the device-specific federal requirements, the claims were preempted.

The Sprint Fidelis court faced similar issues in several hundred cases involving implantable cardiac defibrillators and the small wires, or "ICD leads," that attach to the defibrillator and the patient's heart muscle.

The defendant, Medtronic, manufactured ICD leads from at least 1992 when it obtained PMA for the devices. Since that time, Medtronic developed various types of ICD leads and, in 2003, submitted a PMA supplement for a model entitled the Sprint Fidelis lead, which the FDA approved in 2004.

Based on alleged failures of the leads and a related recall of the products, plaintiffs filed actions alleging claims of negligence, strict products liability, fraud, and breach of warranty.

Medtronic moved to dismiss the claims as preempted by the MDA's express preemption provision because such claims were premised upon a determination that the leads should have been designed, manufactured, tested, marketed, or labeled differently from the manner approved by the FDA during the PMA process.

Relying heavily on Riegel, the Sprint Fidelis court dismissed all claims as preempted. In its analysis,

the court repeatedly referenced the express preemption provision of the MDA, noting that the claims asserted by the plaintiffs would impose requirements "different from, or in addition to" those requirements mandated by federal law and the PMA process through which the ICD leads had been subjected.

For example, with the failure-to-warn claims, plaintiffs alleged that Medtronic failed to provide adequate and timely warnings or instructions regarding the leads.

The court, in finding such claims preempted, noted that if the plaintiffs were successful, Medtronic would have been required to provide warnings above and beyond those on the Sprint Fidelis leads' product label, even though that label was specifically approved by the FDA.

Perhaps most importantly for future precedent, the Sprint Fidelis court rejected two creative arguments by the plaintiffs in their attempt to avoid the impact of Riegel.

First, the plaintiffs argued that once Medtronic recalled the products at issue, it lost the ability to argue preemption as such recall "invalidated" the PMA of the devices. The court rejected this argument as an attempt to conflate a product's recall with the revocation of a device's PMA.

Furthermore, the court noted that PMA approval and attendant preemption attached at the time of approval; it could not be invalidated by events that occurred subsequently. The court noted that "preemption necessarily looks backward (to the time of PMA) rather than forward."

Second, plaintiffs attempted to argue their claims survived under the principal exception to PMA device preemption noted in Riegel; namely that their claims were "parallel" claims — that is, claims that were not "different from, or in addition to" federal requirements.

The court methodically analyzed each of the plaintiffs' claims and rejected the "parallel claims" argument as each claim necessarily sought to impose different and additional requirements on the defendant.

Wyeth V. Levine — The Mother Of All Preemption Cases

While Sprint Fidelis's application of Riegel sends a clear message that the doctrine of federal preemption is overwhelmingly strong in the PMA medical device arena, an upcoming decision by the USSC in Wyeth v. Levine will determine how those principles are applied to pharmaceutical cases.

The issue before the USSC is whether state law failure-to-warn claims involving medicines — that is, claims that a medicine's prescribing information are allegedly inadequate — unduly interfere with and are therefore preempted by the FDA's comprehensive regulation of medicines' prescribing information.

In Wyeth, plaintiff Levine asserted claims in Vermont state concerning injuries associated with her physician's administration of a Wyeth medicine, Phenergan.

Levine's physician administered the medicine through what is known as the "IV push" method which carried additional risks as opposed to the recommended "IV drip" route. The medicine came into contact with arterial blood, causing gangrene and necessitating the amputation of her forearm.

Plaintiff premised her failure-to-warn claim on the theory that Wyeth should have amended its prescribing information to bar the use of the "IV push" administration method.

Wyeth contended that due to the FDA's comprehensive regulation of prescribing information, such failure-to-warn claims necessarily interfered with the FDA's approval process by "second guessing" the balance made by the FDA between appropriate consideration of risk versus benefit to the public.

The plaintiff prevailed in the trial court and Wyeth appealed to the Vermont Supreme Court, which affirmed.

The court held that the failure-to-warn claim was not preempted because, contrary to Wyeth's position, Wyeth could have unilaterally acted to amend the label to preclude use of the "IV push" method even though the FDA had approved the use of the IV push method in certain circumstances.

The USSC granted Wyeth's petition for certiorari and held oral argument on Nov. 3, 2008.

Based upon the briefs and oral arguments, it appears that the USSC has a clear basis to recognize some form of FDA conflict preemption if a majority concludes that the record supports a finding that the FDA considered the risks of the "IV push" administrative method at issue and concluded that Phenergan's labeling was adequate.

At oral argument, Levine's counsel conceded that certain pharmaceutical claims challenging the adequacy of the label could be preempted if the FDA had actually considered a particular issue

reflected in final labeling and no new or different information existed concerning this labeling issue.

Second, critical to the Supreme Court's decision may be the fact that counsel for Wyeth, in response to a question by Chief Justice Roberts as to Wyeth's case in comparison to Riegel and the fact that no express preemption provision exists in relation to drugs, noted that the pre-market approval process for pharmaceuticals was virtually identical to the process for medical devices addressed by the Riegel court.

Therefore, it was immaterial that the FDCA lacked an express preemption provision since the effect of both approval processes, wherein a deliberate risk-benefit evaluation was made by the FDA, was the same. Given the 8-1 result in Riegel, any persuasive tie to the rationale underlying that decision will obviously be helpful to Wyeth's position.

Third, any preemption finding is likely to be narrow and heavily conditioned. Given the totality of the Justices' questions and the parties' responses, it is clear that a broad, sweeping FDA preemption decision is unlikely.

Altria Group Inc. V. Good — Good, Bad Or Ugly For Likelihood Of Preemption In Levine?

Another recent decision by the USSC involving the federal regulation of product labels, though not in the context of pharmaceuticals or medical devices, may shed some light on the outcome in Levine.

In Altria Group Inc. v. Good, No. 07-562, 2008 WL 5204477 (U.S. Dec. 15, 2008), smokers of certain light cigarettes sued the manufacturer and its parent company, Altria Group Inc. ("Altria"), for an alleged violation of the Maine Unfair Trade Practices Act.

Plaintiffs alleged that Altria engaged in the fraudulent marketing of its cigarettes by claiming that its "light" cigarettes delivered less tar and nicotine to consumers than regular brands despite Altria's alleged knowledge that this was untrue.

Altria moved for summary judgment on the grounds that the state-law claim was preempted by the Federal Cigarette Labeling and Advertising Act ("Labeling Act") which protects manufacturers from inconsistent state labeling laws and prohibits the requirement of additional statements relating to smoking and health on cigarette packages.

The Labeling Act provides that no requirement or prohibition based on smoking and health shall be

imposed under state law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of the Act.

After the district court found the claims to be preempted, the United States Court of Appeals for the First Circuit reversed, concluding that the claim was in substance a fraud claim alleging that Altria falsely represented the tar and nicotine content of its cigarettes.

Therefore, even though the alleged misrepresentations were unaccompanied by additional statements in the nature of a warning, that fact did not transform the claimed fraud into a failure to warn claim.

On appeal, the USSC inquired whether the legal duty that was the predicate of the common-law action constituted a requirement or prohibition based on smoking and health with respect to advertising or promotion.

Since the claim at issue alleged a violation of the manufacturer's duty not to deceive — a duty not based on smoking and health — the USSC decided that the Labeling Act did not preempt the plaintiffs' state law claim.

Implicit in the Court's opinion, and its affirmation of the decision of the Court of Appeals, is that a true failure-to-warn claim would be preempted by the Labeling Act.

So, what does this imply for Levine? Not much at this point other than the fact that Altria provided the USSC with a favorable set of facts for preemption, but the basis of preemption between the two cases are substantially different.

First, since true fraud claims against pharmaceuticals are already preempted under the USSC's decision in Buckman v. Plaintiff's Legal Committee, 531 U.S. 341 (2001), the "fraud" rationale for finding no preemption in Altria does not provide a preemption "escape hatch" for Levine.

Second, for failure to warn claims "dressed up" like fraud claims against pharmaceuticals (as most are in this type litigation), these arguably would be preempted under Altria as they would necessarily be challenging an administrative agency's approval of a label.

Therefore, if anything, Altria shows that the current USSC certainly sees boundaries when it comes to federal preemption, even on facts that set up very nicely for a manufacturer.

Conclusion

In the coming year, pending pharmaceutical and medical device litigation will unquestionably be affected by Riegel, Sprint Fidellis and most importantly, Levine. The manner and extent of this impact will develop throughout this and coming years.

Moreover, in addition to the impact these cases will have on litigation, these cases will similarly affect manufacturers' conduct with regard to the approval process as well as their labeling decisions for their products.

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