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Bi-Annual Update Regarding Pharmaceutical and Medical Device Federal Preemption

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The defense of federal preemption continues to be an effective tool for pharmaceutical and medical device manufacturers defending against tort state claims. This Bi-Annual Update provides a summary of preemption decisions and trends issued since our March 2006 edition, which is archived at *www.reedsmith.com/_db/_documents/0608prod_liab.pdf*. It first reviews the impact of the FDA's Final Rule regarding prescription drug labeling, and then provides an update regarding new federal and state decisions on express preemption in medical device cases.

The Impact of the FDA's Final Rule for Drug Labeling

Until fairly recently, federal preemption has been much less of a factor in prescription drug cases than medical device cases because only medical devices are subject to an express preemption clause, 21 U.S.C. section 360k(a).

Despite the absence of an express preemption clause, implied conflict preemption is a defense in some prescription drug failure-to-warn cases, where the plaintiff argues that a drug label should have contained a warning different from what the FDA required.

The defense has been most successful in those cases where the FDA directly evaluated the specific warning the plaintiff advocates in litigation, found it scientifically and medically unjustified, and ordered the manufacturer not to include it in the label. It is less successful without particular FDA consideration of the specific alleged risk giving rise to the litigation. *See*, *e.g.*, *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 929 (2004) (holding that it was impossible for the pharmaceutical manufacturers to comply with both the state-mandated Proposition 65 warnings for over-the-counter smoking cessation product and the FDA's ruling that the Prop. 65 warning could not be included on the label; as a result, plaintiff's state law Prop. 65 warning was preempted); *Dusek v. Pfizer Inc.*, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004) (holding that FDA's regulations could not be considered minimum standards of conduct because the FDA explicitly stated that the plaintiff's proposed warning was inappropriate and would constitute misbranding is used). *Needleman v. Pfizer, Inc.*, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004) (same).

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"Bi-annual Update Regarding Pharmaceutical and Medical Device Federal Preemption" – *continued from page 1*

Some courts still conclude that Congress did not intend any preemption for prescription drugs, whether express or implied.

Plaintiffs frequently responded to conflict preemption arguments by pointing to 21 C.F.R. section 314.70(c)(6)(iii)(A). These FDA regulations, plaintiffs argued, permit drug manufacturers to unilaterally add or strengthen a contra-indication, warning, precaution or adverse reaction without prior FDA approval. Accordingly, so the argument went, a manufacturer's failure to include an additional warning would not in fact put the manufacturer in an untenable position, and thus not result in conflict preemption. Courts that accepted these arguments generally viewed the FDA-approved labeling warnings to be mere "minimum standards" that can and should be supplemented by manufacturers.

The reality of drug labels is quite different, however, and prescription drug preemption received a substantial boost from the FDA's endorsement in its Final Rule, "Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products," released in January. *See* 71 Fed. Reg. 3922 (2006). The Preamble to the Final Rule addresses the preemptive scope for the labeling of pharmaceutical drugs, and states that state law claims can "conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law." *Id.* at 3934 (citing *Dowhal*, 32 Cal. 4th 910). The Preamble further expressly rejects some courts' "misunderstanding" that the FDA labeling requirements represented a "minimum safety standard." *Id.* at 3934-35.

Some courts still conclude that Congress did not intend any preemption for prescription drugs, whether express or implied. Thus, the district court in *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964 (D. Neb. 2006) rejected implied preemption stating that there exists no "congressional directive that the field is preempted." *Id.* at *2. In *Witczak v. Pfizer, Inc.*, 377. F. Supp. 2d. 726, 732 (D. Minn. 2005), the court also stated there was no congressional intent to create implied preemption, and dismissed the FDA's Final Rule as unpersuasive without much discussion. *Id.* And in *Laisure-Radke v. Par Pharm., Inc.*, 2006 WL 901657 (W.D. Wash. March 29, 2006), the court acknowledged the Final Rule, but found no implied preemption for a generic drug manufacturer's decision to not unilaterally strengthen labeling requirements. The unpublished *Coutu v. Tracy*, 2006

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WL 1314261 (R.I. Super. May 11, 2006) decision also paid little heed to the Final Rule by contrasting it with the apparently conflicting comments with respect to preemption contained in the FDA's proposed amendment of 2000. *See* 65 Fed. Reg. 81082, 81103 (2000). This conflict and change in position, the court stated, was cause for questioning the current position taken by the FDA. *Id*. at *4.

Significantly, however, a number of other courts are following the FDA's lead. The courts upholding federal preemption in prescription drug cases conclude that federal labeling requirements for pharmaceutical drugs do impose standards that can conflict with state law tort claims. These courts generally afford considerable deference to the FDA's regulating authority over approved pharmaceutical drugs, particularly in light of the Final Rule and the congressional authority granted to the FDA in implementing and regulating through the FDCA. *See*, *e.g.*, *Abramowitz v. Cephalon, Inc.*, No. BER-L-617-04, 2006 WL 560639, at *3 (N.J. Super. March 3, 2006) (noting Final Rule, and holding because the FDA had assumed regulatory authority over the labeling and approval of pharmaceutical drugs, claims like the plaintiffs' failure-to-warn cause of action was preempted).

One of the most detailed cases analyzing these issues is *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006). The Court began its analysis by recognizing first, that under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984), Supreme Court precedent dictated that the FDA's interpretation of the statute and regulations it administers was entitled to deference. *Id*. at 525. Such deference was particularly warranted in the preemption context, for:

> in the absence of clearly expressed Congressional intent or subsequent developments that reveal a change in that position, the FDA's position on the preemptive scope of its regulatory authority "is dispositive." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714 (1985).

Id.

Keeping in mind this deferential standard, the *Colacicco* court requested and received an FDA amicus brief providing the FDA's views on preemption and the extent to which the court may rely on the agency's views. See Brief for United States as Amicus Curiae Supporting Defendants, *Colacicco v. Apotex*, Civ. No. 05-5500, Doc. No. 45 (E.D. Pa. May 10, 2006) ("Colacicco Amicus"). In the *Colacicco Amicus*, the FDA explained that the plaintiff's failure-to-warn claims premised on the manufacturer's labeling were preempted because the FDA had considered the warnings proffered by the plaintiff, and had rejected them for not being based on reliable scientific evidence. *Id.* at 526–27. Had the manufacturer labeled the medication as the plaintiffs argued, the medication would have been deemed "misbranded" and in violation of 21 U.S.C. § 331(a), (b), (k). *Id.*; *see also Colacicco Amicus*, at *13, 15. The FDA further explained that the Preamble itself was not the "basis for federal preemption," but that it was the FDA's past determination with respect to the scientific reliability of the labeling that conflicted with the state law claims. *Colacicco*, 432 F. Supp. 2d at 537. Moreover, the court in *Colaccio* found the Preamble consistent with prior FDA amicus briefs filed in *Kallas v. Pfizer*, Civ. No. 2:04-cv0998 (D. Utah Sept. 15, 2005) and *Motus v. Pfizer, Inc.*, 2002 WL 32303084 (9th Cir. Sept. 10, 2002). *Colacicco*, 432 F. Supp. 2d at 527.

In doing so, the court discounted countervailing arguments with two observations. First, the FDA's brief was not legal argument but involved the FDA's "unique[] qualifi[cation] to comprehend the likely impact of state requirements." *Id*. at 529–32 (citing *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883 (2000) and *Medtronic v. Lohr*, 518 U.S. 470, 496 (1996)). Second, even though there were pre-2000 proposed FDA comments with a different stance on preemption, on four more recent occasions the FDA strongly supported preemption (in the *Colacicco Amicus*, the Final Rule, the *Kallas Amicus*, and the *Motus Amicus*). *Id*. at 531–32.

A judge in the Northern District of California also recently deferred to the FDA's interpretation of the preemptive scope of its regulatory actions in light of the technical subject matter involved in prescription drug regulation, the FDA's regulatory role under the FDCA, and the likelihood that the FDA has "'a thorough understanding of its own regulations and its objectives.'" *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 2006 WL 2374742, at *6 (N.D. Cal. Aug. 16, 2006) (quoting *Geier*, 529 U.S. at 883).

The court in *In re Bextra* further dismissed several arguments that the FDA's Final Rule preamble does not deserve deference. First, the court established that the Final Rule did constitute a regulation entitled to the court's consideration or deference, citing *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707,

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"Bi-annual Update Regarding Pharmaceutical and Medical Device Federal Preemption" – *continued from page 3*

718 (1985), which found that agencies could address problems "through a variety of means, including regulations, preambles, interpretive statements, and responses to comments. 2006 WL 2374742, at *7. Second, the court confirmed that Congress did delegate responsibility to the FDA to administer the FDCA. And finally, the court dismissed charges that the FDA took inconsistent views on preemption over time, noting that the Supreme Court has recognized agencies may change their views over time as they gain "more experience with the interrelationship between its regulations and state laws. *Id*. at *8 (citing *Hillsborough*, 471 U.S. at 714–15; *Chevron*, 467 U.S. at 863–64).

While it remains to be seen how additional courts will respond to implied preemption arguments, the FDA's Final Rule has made it somewhat easier for defendants to assert conflict preemption as a first line of defense in those prescription drug cases where the regulatory history clearly shows careful FDA consideration and control over the very type of warning being challenged in a failure to warn lawsuit.

Most recently, a magistrate judge in the Eastern District of Texas filed a report and recommendation on Sept. 8, 2006 recommending summary judgment for the manufacturer of an SSRI anti-depressant on preemption grounds in *Ackermann v. Wyeth Pharmaceuticals*, 2006 WL 2591078 (E.D. Tex. Sept. 8, 2006). In *Ackermann*, the plaintiff alleged that Wyeth failed to warn that the drug carried an increased risk of suicide but, as the magistrate judge noted, the FDA had repeatedly examined this very issue several times over the years and determined that a different warning was unwarranted. Although the magistrate judge found the issue to be a "close question," ultimately the FDA's position on preemption tipped the balance in favor of recommending preemption. Plaintiffs' objections to the report and recommendation are due Sept. 22, 2006.

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Other Implied Preemption Cases

In March, a federal court in Wisconsin considered implied preemption arguments in a case involving over-the-counter Prilosec (although FDAMA contains an express preemption clause for non-prescription drugs, it also contains a savings clause which *exempts product liability* actions from the reach of its express preemption provision, *see* 21 U.S.C. § 379r(e) & s, making implied preemption). In *Peters v. Astrazeneca*, 417 F. Supp. 2d 1051 (W.D. Wis. 2006), on a motion to dismiss, the district court rejected the argument that the FDA's regulation of drugs is so pervasive that Congress intended field preemption. It also concluded that because there was no factual record demonstrating what the FDA had evaluated and required on the Prilosec label, conflict preemption had not been established.

Unfortunately, in doing so, the court also stated that FDA drug labeling requirements impose only "minimum standards" that are open to supplementation by state law, although it does not appear that *Peters* considered the FDA's Final Rule in so doing. Given that some courts, like the court deciding *Peters*, have some resistance to preemption, it may be more effective long term for manufacturers to forgo field preemption arguments (which are not well-supported by case law and which exceed the FDA's position on preemption in the Final

Rule) and raise conflict preemption arguments within the context of well-developed regulatory factual records.

In addition, a California court has considered implied preemption arguments in an interesting case involving food labeling, *In re Farm Raised Salmon Cases*, 2006 WL 2510152 (Cal. App. Aug. 31, 2006). In *Farm Raised Salmon*, the court held that California unfair business and false advertising claims—premised on the allegedly misleading practice of enhancing the color of farm-raised salmon through special feed—were preempted, because the claims depended on proof that defendants had violated certain FDCA provisions. The court noted that the FDCA contains a "no private right of action" clause that prevented direct claims, and also that implied preemption principles prevented plaintiffs from arguing that an FDCA violation had occurred when the FDA itself had not made that determination. *Id*. at *4–*5.

Recent Express Preemption Cases

Since our last preemption update in March 2006, two additional circuit decisions and one state decision rendered have joined the majority view cases holding that the express preemption clause of the Medical Devices Amendment triggers preemption for those Class III, pre-market approved medical devices that are challenged by state law tort claims imposing different or additional requirements.

In the first, the Fifth Circuit in *Gomez v. St. Jude Medical Daig Division, Inc.*, 442 F.3d 919 (2006), followed circuit precedent, *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) and *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), in holding that the PMA approval of a medical device preempted the plaintiff's defective design, failure-to-warn, and implied and express warranty claims. *Id*. at 933.

In doing so, however, the reviewing panel affirmed the lower court's decision to deny summary judgment on the defective manufacturing claim—that the plaintiff's device "deviated from the FDA-approved specifications in manufacturing the [device] used." *Id*. at 932. Nevertheless, because the plaintiff failed to proffer any evidence supporting this claim, it, too, was dismissed. *Id*.

Plaintiffs often respond to the preemption defense by pointing to authorities noting that manufacturing defect claims survive preemption, and then try to argue that design defect or failure-to-warn theories actually fit under the "manufacturing defect" rubric. As a result, *Gomez* is quite helpful authority regarding what a true manufacturing defect is, and why such an exception is quite narrow.

Likewise, in a case briefed by Richard Bakalor of Quirk and Bakalor, and Michael K. Brown and Lisa M. Baird of Reed Smith LLP and argued by Michael K. Brown, the Second Circuit "join[ed] the growing consensus" of those courts holding that tort claims alleging liability for PMA-approved medical devices adhering to its approved requirements were preempted. *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006). Similar to *Gomez*, the *Riegel* majority opinion carefully limited its holding to the "small universe of cases resting on claims alleging liability despite a PMA-approved device's adherence to the standards upon which it secured FDA premarket approval." *Id*. Those tort claims premised on the manufacturer's alleged departure of those standards, such as the negligent manufacturing claim, were not preempted.

The dissent in *Riegel*, however, departed from the majority by focusing its analysis on the presumption against preemption and congressional intent. *Id*. at 128. The opinion found a lack of clear congressional intent to preempt state tort claims, particularly in light of "Congress' failure to provide any federal remedy for persons injured by such conduct." *Id*. at 129 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S 238, 251 (1984)). In the dissent's view, the success of the PMA process constituted nothing less than a finding that the device met the FDA's minimum requirements for safety and effectiveness, and were not sufficient for triggering preemption. *Id*. at 132. A petition for certiorari to the Supreme Court was filed in *Riegel* on Aug. 3, 2006, by the Public Citizen, whose cert petition was denied in *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005), *cert. denied sub nom. Knisley v. Medtronic, Inc.*, 126 S.Ct. 420 (2005).

Judge Richard J. Sankovitz of the Circuit Court in Milwaukee County, Wisconsin—in a state with no prior medical device preemption cases on the books—granted summary judgment for Medtronic on the basis of federal preemption briefed by Michael K. Brown, Lisa Baird, and Mildred Segura of Reed Smith, along with Lori G. Cohen and Jay B. Bryan of Greenberg Traurig, and Thomas J. Arenz and Pamela M. Schmidt of Whyte Hirschboeck Dudek S.C., and argued by Michael K. Brown. *Blunt v. Medtronic*, Case No. 05CV003879 (Wis. Cir. Court April 4, 2006).

In a comprehensive decision, the court thoughtfully joined the majority

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"Bi-Annual Update" – *continued from page 5*

view by holding that the PMA-approved specifications "*required* [manufacturers] to market what had been approved" and that state law tort claims would be the kind of "substantive requirement" that should be preempted. *Id*. at p. 10 (original emphasis), p. 22. In doing so, the court rejected plaintiff's suggestion that the FDA's review of a particular component was not that rigorous:

> the FDA's approval of the device as a whole might shield the individual components of the device from state law claims, regardless of how much, *if any*, actual attention those individual components were given by the manufacturer and the FDA.

Id. at 12. Thus, the PMA approval was sufficient to give rise to specific requirements with preemptive effect. Plaintiffs have filed a notice of appeal in *Blunt*, and briefing will take place over the next few months.

Finally, in a case involving a less-regulated, Class I medical device (latex gloves), a judge in the Southern District of New York concluded that the FDA's 200-page document titled *Regulatory Requirements for Medical Gloves: A Workshop Manual*, did not preempt plaintiff's failure-to-warn claims, because it did not constitute a federal requirement even though it contained regulations specifically governing latex gloves. *Adesina v. Aladan Corp.*, 438 F. Supp. 2d 329 (S.D.N.Y. 2006). At least one other court has reached the opposite conclusion regarding latex glove failure-to-warn claims, however. *See Busch v. Ansell Perry*, 2005 WL 877805 (W.D. Ky. 2005).

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