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Product Liability Update

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Bi-Annual Update Regarding Pharmaceutical Drug and Medical Device Federal Preemption: The Supreme Court Speaks In *Riegel v. Medtronic*

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Our last Biannual Preemption Update, published in October 2007, ended on a hopeful note about the drug and device preemption cases before the U.S. Supreme Court, and how such decisions might shape the defense and assist manufacturers. The first of these decisions, *Riegel v. Medtronic, Inc.*, — S.Ct. —, 2008 WL 440744, released by the Court Feb. 20, 2008, provides cause for celebration, even as the life sciences industry awaits the resolution of two other cases before the Court.

In addition to reviewing the Supreme Court preemption activity, this article reviews lower court drug and device preemption decisions issued since October 2007, and federal legislative and regulatory activity with the potential to impact the preemption defense.

U.S. Supreme Court Activity In Medical Device and Drug Preemption Cases

Riegel v. Medtronic, Inc., — S.Ct. —, 2008 WL 440744 (U.S. Feb. 20, 2008) (No. 06-179)

In the *Riegel* decision, the Supreme Court readily held that the express preemption provision of the Medical Device Amendments to the Food, Drug and Cosmetic Act ("FDCA") preempts state law claims seeking damages for injuries caused by medical devices that received premarket approval ("PMA") from the FDA. In a marked contrast to the fractured *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) decision involving the same preemption statute and a 510(k)-cleared device, seven justices joined the majority opinion, authored by Justice Scalia, while Justice Stevens wrote a short concurrence and Justice Ginsburg was the sole dissenter. It is safe to say *Riegel* is a landmark decision that flatly rejected the small number of minority view cases involving PMA devices.

In *Riegel*, the Court first concluded that FDA's premarket approval imposes "specific requirements applicable to a device," and that federal law forbids manufacturers from deviating from FDA-approved "design specifications, manufacturing

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processes, labeling, or any other attribute." It also concluded that common law negligence and strict liability claims impose state "requirements" as that term is ordinarily understood when used in preemption statutes, and that the *Riegel* plaintiff's tort claims were preempted because they sought to impose state requirements on the relevant medical device that were "different from, or in addition to," the federal requirements.

At the same time, the Court was careful to note the limits of *Riegel*—namely, that the case did not present claims in which the state duties were "parallel" to, rather than different from, or in addition to, federal requirements. Given that many plaintiffs frame their allegations precisely this way—as mirroring rather than supplementing federal requirements—further litigation over the scope of this theoretical preemption "exception" is likely.

At the same time, the Court was careful to note the limits of* Riegel*—namely, that the case did not present claims in which the state duties were 'parallel' to, rather than different from, or in addition to, federal requirements.

Apart from the "parallel" claim exception, Justice Ginsburg's dissent includes a footnote that plaintiffs also may try to exploit. Footnote 1 of her dissent states: "The Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device's defect comes to light only *after* the device receives premarket approval." Plaintiffs undoubtedly will argue that the circumstances of their cases fit within this footnote and that preemption thus does not apply. If taken at face value, Justice Ginsburg's footnote would swallow the Court's holding, given that covered medical devices cannot be sold before premarket approval is granted, and allegations of product defect ordinarily would only crop up after approval. The majority opinion, however, contains no indication that the express preemption clause is without force in a case where the "defect comes to light only after premarket approval." The facts of *Riegel* itself also undermine this assertion, in that the plaintiff's allegations were that the FDA granted premarket approval to the device in question, and then the device malfunctioned during an operation on plaintiff; the plaintiff did *not* contend that the manufacturer (or the FDA) knew of a device "defect" prior to premarket approval. Ultimately, this passing comment in dissent should merit little deference or attention.

Other aspects of the majority opinion also are interesting. To begin with, the Court made no mention of the Circuit split that its decision resolved, citing neither majority view cases—save the Second Circuit's decision under review—nor the minority view case, *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999). Since the Court seemingly viewed the issue as a relatively straightforward statutory construction exercise, there certainly was no need for it to rely on or address any of the circuit level decisions. At the same time, the majority view preemption cases contain a wealth of analysis and involve application of the preemption statute in various circumstances, and some discussion of them would not have been out of place.

In addition, the majority opinion made no mention of the "presumption against preemption," a concept discussed only by Justice Ginsburg in her dissent. As Justice Ginsburg noted, some of the Court's earlier cases have stated that in divining Congressional intent regarding preemption, the analysis "starts with the assumption" that preemption was not intended. If the presumption against preemption is viewed, however, as a principle of statutory construction that comes into

play only when the statutory language is ambiguous—and does not when the Congressional intent to preempt is "clear and manifest"—the Court's silence is less mysterious. The majority found nothing ambiguous about the MDA's express preemption provision, and viewed the plain statutory language as ample proof of Congressional intent.

The Court was also seemingly unfazed by arguments premised on 21 C.F.R. § 814.39. Plaintiffs argue that this regulation gives manufacturers room to freely revise their labels and deviate from the warning language mandated through the premarket approval process. In fact, the Solicitor General addressed this issue, including in a supplemental letter to the Court Jan. 16, 2008, that attached a proposed rule to amend 21 C.F.R. § 814.39(d) and clarify the "agency's longstanding view" that manufacturers have no discretion to implement changes without the FDA's consent. In the end, plaintiff's arguments about the meaning of 21 C.F.R. § 814.39 went entirely unmentioned. The Court instead cited to 21 C.F.R. § 814.39 for the proposition that applicants who wish to deviate from FDA-mandated requirements must obtain FDA approval for a PMA supplement detailing the change.

The *Riegel* decision was issued just over two months following the oral argument, which was held Dec. 4, 2007. As set forth in the box below, some of the questions posed by the Justices during the argument are echoed foreshadowed the opinions about whether juries engage in the same kind of balancing inquiry undertaken by the FDA during the premarket approval process, and how the medical device approval process and preemption inquiry differ from those applicable to drugs.

In terms of what *Riegel* may portend for future life sciences preemption cases, it is safe to assume that medical device product liability plaintiffs will attempt to position their claims as relying on standards that simply "parallel" federal requirements, even when

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Oral Argument Insights

Justice Kennedy [To Counsel for Riegel]: Well, before that decision is reached, let me ask you this—under State law, either generally or specifically under the law of the State that you are trying to invoke here, does the jury—does the finder of fact weigh the potential risks of injury and illness against the probable benefits to the health of the patient? Is that one of the things the jury does? In other words, suppose this was a very important device, but it had a one percent risk. Does the jury consider that when it determines whether that's been negligently sold? (Transcript, available at http://www.supremecourtus.gov/oral_arguments/argument_transcripts.html, 6:10-20)

Justice Scalia [To Counsel for Riegel]: Of course, this is all a little unrealistic. It is not as though some expert agency of the State has conducted a very scientific inquiry and decided that there's something safer than what the FDA approved or that it's negligent to issue what the FDA approved. What's going on is simply one jury has decided that in its judgment, there was a safety device that should have been used; and because of the judgment of that one jury, the manufacturer is placed at risk in selling a device that scientists at the FDA have said is okay. I find that extraordinary. (19:12-23)

Justice Ginsburg [To Counsel for Riegel]: …—as I understand it, tort suits are not preempted with respect to new drugs. Is there a reason to treat the two differently? For new medical devices and the new drugs? (9:17-20)

Justice Ginsburg [To Counsel for Riegel]: Another variation—the FDA says you must include X in this device or we won't give the pre-market approval. And so the manufacturer puts X in, and then there's a lawsuit that wants to charge that putting X in made the device dangerous. Would the FDA's insistence that X be put in take X out of any State court's tort litigation? That is, wouldn't—if the FDA says you must have it, a State court couldn't put to a jury whether you should have eliminated it? (16:12-22)

Justice Ginsburg [To Counsel for Medtronic]: Mr. Olson, what about the argument that once you've got this very valuable pre-market approval, even though you could make that device safer, you have no incentive to do that. You have permission to market this product as is. Even if you know that there's a better way to do it, there's a disincentive to try to go through the process and make the change. Why should you, when you have carte blanche to continue without make the change? (35:15-23)

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In terms of what Riegel *may portend for future life sciences preemption cases, it is safe to assume that medical device product liability plaintiffs will attempt to position their claims as relying on standards that simply 'parallel' federal requirements, even when they in fact are not.*

they in fact are not. Existing majority view authorities do provide some help in dealing with supposedly "parallel" allegations, however. For example, in *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 488-89 (7th Cir. 2006), the court examined whether plaintiff's state law claims were the "genuine equivalent" of the FDA-imposed federal requirements, concluded they were not actually parallel, and upheld express preemption.

In other cases, such as the Second Circuit's opinion in *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 123 (2d Cir. 2006), as well as *Gilleon v. Medtronic, Inc.*, 2002 WL 31300694 (N.D. Cal. 2002), and *Carey v. Shiley, Inc.*, 32 F. Supp. 2d 1093, 1106-07 (S.D. Iowa 1998), courts have recognized that any "parallel" exception to express preemption is narrow, applying only where the defendant's alleged non-compliance resulted in a device physically different from the one the FDA approved, or with labeling other than what the FDA approved. If a plaintiff's allegations depend on supposedly "parallel" duties falling outside these narrow areas, implied preemption principles and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001), may have application. *See Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005) (claims that manufacturer should have recalled product earlier and failed to comply with specified reporting and other federal regulations were "disguised fraud on the FDA" claims and preempted); *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36, 39 (D.D.C. 2003) (allegations that defendant failed to properly investigate and report to the FDA did not support warning or fraud claims but rather were preempted under *Buckman*). Furthermore, the FDCA contains a "no private right of action clause," 21 U.S.C. § 337(a), which also limits plaintiffs' ability to sue directly for alleged FDCA violations. *See Kemp v. Medtronic*, 231 F.3d 216, 235-36 (6th Cir. 2000) (noncompliance claims violate no private right of action clause).

Finally, since the majority was careful to adhere closely to the MDA express preemption statute, on the surface the case has limited application to the prescription drug context that rests on different preemption principles. Some aspects of *Riegel* nevertheless may have significance outside the medical device context. In dicta, the majority stated that because the FDA's position on preemption has changed over time, the agency's position might only warrant a reduced amount of deference. Since plaintiffs argue that the agency's position on preemption in the drug context likewise has changed over time, arguments regarding reduced deference may resurface in the Supreme Court's other preemption cases. On the other hand, even the sole dissenter, Justice Ginsburg, made seemingly positive references to implied conflict preemption, arguing that "a medical device manufacturer may have a dispositive defense if it can identify an actual conflict between the plaintiff's theory of the case and the FDA's" approval requirements, even as she rejected express preemption.

Warner-Lambert Co. v. Kent, cert. granted *128 S.Ct. 31 (U.S. Sept. 25, 2007) (No. 06-1498)*

The second Supreme Court preemption decision affecting the life sciences industry will come in *Warner-Lambert Co. v. Kent*. The case is set for oral argument Feb. 25, 2008, and the transcript should be available later that day at *http://www.supremecourtus.*

gov/oral_arguments/argument_transcripts.html. As in *Riegel*, the Solicitor General, appearing in the case as an *amicus*, will participate in oral argument. The Court's decision will be issued sometime this term, with the last day of the term being June 23, 2008.

Warner-Lambert will address an exception to a Michigan statute that provides immunity from product liability lawsuits for drug manufacturers who comply with FDA labeling requirements. The exception allows liability upon proof that the manufacturer defrauded the FDA, and *Warner-Lambert* presents the question of whether this exception violates *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which held that affirmative "fraud on the FDA" claims are preempted.

After their petition for review was granted Sept. 25, 2007, Warner-Lambert Company and Pfizer filed their brief Nov. 21, 2007 [2007 WL 4205142], followed by a quick succession of amicus curiae briefs in support: the United States [2007 WL 4218889], Pharmaceutical Research and Manufacturers of America [2007 WL 4218888], Product Liability Advisory Council [2007 WL 4218013], Chamber of Commerce of the United States of America [2007 WL 4205141], Generic Pharmaceutical Association [2007 WL 4218887], and Washington Legal Foundation [2007 WL 4232927].

Respondents filed their merits brief Jan. 11, 2008 [2008 WL 157174], and amicus curiae briefs were filed by Kansas [2008 WL 189544], the American Association for Justice [2008 WL 177562], Public Justice PC [2008 WL 189551], AARP [2008 WL 189550], and the National Conference of State Legislatures, *et al.* [2008 WL 194280].

Wyeth v. Levine, rev. granted, — S.Ct. —, 2008 WL 161474 (Jan. 18, 2008) (No. 06-1249)

The third life science's preemption case before the Court is *Wyeth v. Levine*. At the Court's request, the Solicitor General filed an *amicus* brief [2007 WL 4555760] suggesting that the Court defer decision on the cert petition until after *Riegel* and *Warner-Lambert* were decided. Nevertheless, on Jan. 18, 2008 the Court granted certiorari, and the case presents the question of whether prescription drug labeling requirements imposed by the FDA preempt state law claims premised on a theory that different warnings should have been given instead. The case will be argued in the October 2008 term; in the meantime, the petitioner's brief is due May 26, 2008.

Express Preemption In The Lower Courts

State Courts

Even as preemption activity in the Supreme Court has reached a fever pitch, over the past six months courts have continued to address the doctrine of express preemption in a favorable and thoughtful manner.

Although over the past decade a majority view had coalesced around the understanding that the Medical Device Amendment's express preemption clause disposes of state tort claims that would impose requirements different from what the FDA mandated, California had not addressed the express preemption since 1997. In *Steele v. Collagen Corp.*, 54 Cal. App. 4th 1471 (1997), a California appellate court held that premarket approval can trigger preemption for state law claims, but at the same time required manufacturers to affirmatively establish their clear compliance with federal requirements to take advantage of the defense. A prior decision, *Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580 (1996), had followed pre-*Lohr* authority and held state law claims did not constitute state law requirements triggering preemption—a view *Riegel* has now unambiguously rejected.

The two most recent California appellate decisions, *Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039 (Jan. 11, 2008) and *Jessen v. Mentor Corp.*, — Cal. Rptr. 3d —, 2008 WL 142824 (Cal. App. Jan. 16, 2008), are a one-two punch favoring preemption. They also are consistent with the Supreme Court's subsequent *Riegel* decision, which has since definitively resolved these issues.

In *Blanco*, the decedent's family brought negligence, strict liability, breach of express and implied warranty claims against a manufacturer of a voluntarily recalled, Class III premarket approved heart valve. A post-mortem review of the implanted heart valve indicated that it suffered from the same alleged defect (leaflet escapes) for which the voluntary recall was initiated.

The reviewing court upheld preemption of state law claims for negligence, strict liability and express warranty based on the valve's PMA approval. It followed the majority view in holding that the premarket approval results in federal requirements that preempt conflicting state law requirements created by the state law claims. *Id.* at *23–*27.

Blanco is notable in part because it involved a Class I voluntary Recall that the manufacturer undertook, and plaintiffs frequently argue that the fact of a recall undermines the FDA's

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approval and the preemption defense. The Court rejected such arguments, stating: "The fact the FDA implemented a Class I recall of the Valve does not alter our conclusion. When the Valve was implanted in [plaintiff], it had been approved by the FDA through the PMA process." *Id*. at *33 (citing *Baker v. St. Jude Medical, S.C., Inc.*, 178 S.W.3d 127, 134 (2005)). The court recognized that there was no evidence in the record to support the conclusion that the FDA revoked the valve's approval. *Id*. at *34.

The fact the FDA implemented a Class I recall of the Valve does not alter our conclusion. When the Valve was implanted in [plaintiff], it had been approved by the FDA through the PMA process.

Jessen involved a Class III testicular prosthesis. Device instructions directed the filling of the prosthesis with saline solution before implantation, but in plaintiff the prosthesis was implanted without filling. After an alleged adverse reaction, Jessen filed strict liability, negligence and breach of warranty claims, arguing that the warnings about saline solution should have been placed on the product's outside packaging, and claiming the manufacturer failed to comply with the federal requirements (a label change imposed months after his surgery).

The *Jessen* court concluded that for preemption, it is compliance with federal requirements in effect at the time of surgery that matters, and that the device had premarket approval. *Id.*, citing *Scott*, 38 Cal. App. 4th at 321 (the unmodified product that was purchased by plaintiff was still subject to Class III MDA regulations at the time of the injury despite approval of a second modified product). *Jessen* thus also upheld preemption and dismissed its claims.

Unlike California, Arkansas—in a pre-*Riegel* decision—did not give preemption as favorable a reception. In *Despain v. Bradburn*, — S.W.3d —, 2008 WL 324356 (Ark. Feb. 7, 2008), the Arkansas Supreme Court reversed summary judgment based on express preemption in a case involving a Class III, PMA-approved hearing device. Although the Supreme Court has since rejected these arguments in *Riegel*, Arkansas did not think that "general tort claims" like strict liability, negligence and breach of warranties could be specific state requirements, or that premarket approval results in federal requirements specific to a particular device. *Id.* at *9, citing *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375 (11th Cir. 1999). Given *Riegel*, *Despain* already is consigned to the dust bin, since the Supreme Court reached the opposite conclusion.

Federal Courts

Over the past six months, favorable express preemption decisions in line with *Riegel* also have been handed down in federal district courts sitting in New Jersey and Louisiana. In *Herbert v. Mentor*, 2007 WL 2893387 (D.N.J. Sept. 28, 2007), the federal court followed the Third Circuit's holding in *Horn v. Thoratec Corp.*, 376 F.3d 163, 164-77 (3d Cir. 2004), and concluded that Section 360k(a) of the MDA preempted the strict liability and breach of implied warranty claims made against the manufacturer of plaintiff's PMA-approved PMA breast implants.

Similarly, in *Mathis v. E.I. DuPont De Nemours and Co.*, 2008 WL 162156 (W.D. La. Jan. 16, 2008), the district court held that the state law products liability and negligent failure-to-warn claims brought against the manufacturer of a Teflon-based paste used for stabilizing paralyzed vocal cords were preempted. The interesting twist in this case comes from the product's regulatory history, reminiscent of

Brooks v. Howmedica, 273 F.3d 785 (8th Cir. 2001). The Teflon-based paste was approved before the Medical Device Amendments were enacted through the New Drug Application process. *Id.* at *1. The Medical Device Amendments classified such products as "transitional devices," and automatically designated them Class III medical devices deemed to have premarket approval provided they had completed the NDA approval process. *Id.* at *3. Having concluded the case involved a PMA medical device, the court analyzed the claims accordingly and agreed with the majority view upholding preemption in such circumstances. *Id.* at *6.

Preemption and *Buckman*

As mentioned above, in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court employed an implied conflict preemption analysis to conclude that "fraud on the FDA" claims are preempted because they threaten too much interference with the FDA's regulatory scheme. In *Wawrzynek v. Statprobe, Inc.*, No. 05-1342 (E.D. Pa. Oct. 25, 2007), a bio-statistical firm and contract research organization, Statprobe, assisted a manufacturer, Gliatech, in carrying out an FDA-mandated clinical study of the medical product. After Gliatech was prosecuted for allegedly altering the clinical trial results, plaintiff sued Statprobe for fraud and Statprobe responded that such fraud allegations were impliedly preempted under *Buckman* because they essentially amounted to fraud on the FDA claims.

The Eastern District of Pennsylvania disagreed, concluding that because the FDA already had determined that the manufacturer committed fraud, the concerns that motivated the preemption result in *Buckman* were not present. Plaintiff's lawsuit posed no threat to the federal regulatory scheme because in *Wawrzynek*, there was no need for "speculation as to the FDA's behavior in a counterfactual situation." *Id.* at 17, quoting *Buckman*, 531 U.S. at 354.

Implied Preemption In The Lower Courts

Pharmaceutical Litigation

Since our last update in October 2007, many litigants and courts have been waiting for appellate courts to provide guidance on implied conflict preemption principles in prescription drug cases. Guidance should come when the Supreme Court decides *Wyeth v. Levine* next term, but lower courts continue to address these issues too. The Third Circuit heard oral argument in *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), *rev. pending* No. 06-3107 (3d Cir. Dec. 29, 2006) and *McNellis v. Pfizer, Inc.*, 2005 WL 3752268 (D.N.J. Dec. 29, 2005) Dec. 10, 2007, but no decision has been issued yet. Similarly, in the Fifth Circuit, *Ackermann v. Wyeth*, 2006 WL 2591078 (E.D. Tex. Sept. 8, 2006), *rev. pending* No. 06-41774 (Dec. 28, 2006), was heard Dec. 3, 2007, but no decision has been issued.

At least two district courts have addressed the issue, however. Both the Western District of Oklahoma and the Eastern District of California addressed implied conflict preemption in cases alleging that manufacturers failed to adequately warn about the risk of suicidality from anti-depressant drugs. *Dobbs v. Wyeth Pharm.*, — F. Supp. 2d —, 2008 WL 169021 (W.D. Okla. Jan. 17, 2008) (failure-to-warn claim for antidepressant prescription for adult patients); *O'Neal v. Smithkline Beecham Corp.*, 2008 WL 274782 (E.D. Cal. Jan. 30, 2008) (failure-to-warn claim for antidepressant prescription for pediatric patients).

For both cases, manufacturers were up against the standard argument that they should have added this warning through FDA regulations that allow manufacturers to make certain label changes while awaiting FDA approval. *See Dobbs*, 2008 WL 169021, *6; *O'Neal*, 2008 WL 275782 ("Changes Being Effected" Supplement under 21 C.F.R. § 314.70(c)(6)(iii) allows for a manufacturer's label change and use prior to FDA approval where the warned harm has a "reasonable evidence of an association with a drug"). In rebuttal, the manufacturers argued that in light of the FDA's express rejection of plaintiffs' suicidality warnings on labels for antidepressant medications during the time period the decedents took the medication, manfuacturers faced a "conflict in complying with the FDA regulations and Plaintiff's interpretation of [state] common law tort obligations." *Dobbs*, 2008 WL 169021, at *6; *see also O'Neal*, 2008 WL 275782, at *8 (holding that a direct conflict of law exists because the manufacturer could not have been in compliance with federal law and also included the suicidality warning plaintiff insisted upon).

Based on this narrow ground of conflict, the courts in both *Dobbs* and *O'Neal* concluded that implied preemption principles prevented the state law failure-to-warn claims from proceeding. *Dobbs*, 2008 WL 169021, at *14; *O'Neal*, 2008 WL 275782, at *14. What the courts did not rely upon, however, was FDA's

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views favoring preemption. In *Dobbs*, the court reviewed *amicus* briefs filed by the FDA and the 2006 Preamble to the labeling regulations, and held that based on its particular facts, deference was not required because the instant case presented a narrower issue. *Dobbs*, 2008 WL 169021, at*13. In *O'Neal*, the court took an even stronger line, stating that because its facts presented conflict preemption, there was no need for any formal statement of congressional intent to preempt or any evidence of the agency's view. *O'Neal*, 2008 WL 275782, *7.

Based on this narrow ground of conflict, the courts in both* Dobbs *and* O'Neal *concluded that implied preemption principles prevented the state law failure-to-warn claims from proceeding.

Food Products

On Feb. 11, 2008, the California Supreme Court concluded that FDCA section 337(a) does not preempt California unfair business and false advertising claims based on the allegedly misleading practice of altering the color of farm-raised salmon through special feed. *In re Farm Raised Salmon Cases*, No. S147171 (Cal. Feb. 11, 2008) *rev'd* 48 Cal. Rptr. 3d 449 (Cal. App. 2006). The lower courts determined that such claims were preempted, because the claims depended on proof that defendants had violated certain FDCA provisions, while the FDCA contains a "no private right of action" clause. The lower courts also had concluded that implied preemption principles prevented plaintiffs from arguing that an FDCA violation had occurred when the FDA itself had not made that determination.

The supreme court, however, concluded that plaintiffs' claims were premised on state requirements that paralleled those imposed by the FDCA, and concluded that the no private right of action clause had no applicability to a claim asserted under state law.

Recent Legislation

On Oct. 1, 2007, the "Food and Drug Administration Amendments Acts of 2007" ("FDAAA") (P.L. 110-85) went into effect. These amendments represent the most comprehensive overhaul of food and drug law since the Food and Drug Administration Modernization Act of 1997. Notable changes include increased FDA authority to monitor and address drug safety issues post-approval. For one, the FDA can require any application holder to conduct post-approval studies or clinical times if the Agency, at any time after approval becomes aware of "new safety information." FDAAA § 901(a). Further, at any time, the FDA can require post-approval labeling changes to strengthen safety information on prescription drugs. FDAAA § 901(a). Finally, either as part of the initial approval or post-approval, the FDA may determine that a "Risk Evaluation and Mitigation Strategies" ("REMS") plan is necessary to help ensure that the benefits of a drug continue to outweigh the risks of a serious adverse drug experience. FDAAA § 901(b). If such a determination is made, the applicant must propose the REMS plan within a statutory deadline and must include follow-up assessments at regular mandated intervals. Failure to comply with these new post-approval requirements may result in a drug being considered misbranded and may result in civil penalties. FDA § 902(a), (b). These amendments further cement the FDA's post-approval regulatory powers. For further information on these amendments, see Reed Smith Food and Drug Law Client Memo on the "FDA Amendments Act of 2007" at *http://www.reedsmith.com/publications.cfm?cit_id=16812&widCall1=customWidgets.content_view_1&usecache=false*.

On Jan. 16, 2008, the FDA issued a proposed rule change to clarify the meaning of its "Changes Being Effected" rules for prescription drugs and medical devices. 73 Fed. Reg. 2848 (Jan. 16, 2008). Currently, under 21 C.F.R. § 314.70, pharmaceutical manufacturers are permitted to change their labels to add or strengthen a contraindication, warning, precaution or adverse reaction without waiting for approval by the agency of such a change, through a "Changes Being Effected" supplement. A similar regulation, 21 C.F.R. § 814.39 exists for medical devices. As noted above, plaintiffs often point to these regulations to argue that manufacturers have freedom to initiate labeling changes regardless of FDA labeling requirements. This proposed rule would further curtail this argument, by making clear that FDA approval still is required, and limiting use of the procedure to circumstances where there is "evidence of a causal association" substantiating the stronger warning, and where the change is based on new information not previously submitted to the FDA. 73 Fed. Reg. at 2850.

Members of Congress responded quickly. On Jan. 23, 2008, House Representatives Henry A. Waxman, John D. Dingell, Frank Pallone, Jr., Rosa L. DeLauro, and Edward Markey, and Senators Edward M. Kennedy, Patrick L. Leahy and Christopher J. Dodd wrote to the FDA, questioning the basis of the FDA's proposed rule, and pointing out that it was "immediately cited" by the Solicitor General in letters to the Supreme Court filed in the three pending life sciences preemption cases, *Riegel v. Medtronic, Inc.*, No. 06-179; *Warner-Lambert Co., LLC v. Kent*, No. 06-1498; *Wyeth v. Levine*, No. 06-1249.

Miscellaneous Cases

Advertising, the Lanham Act And the FDCA

In pharmaceutical advertising, the Lanham Act and the FDCA can come into conflict. In such circumstances, courts generally explain that the FDCA's primary concern is for the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of the advertising claims. *See Axcan Scandipharm Inc. v. Ethex Corp.*, 2007 WL 3095367, *4 (D. Minn. Oct. 19, 2007). Preemption issues arise, however, because allegedly false statements that give rise to Lanham Act litigation may be deemed truthful and within the purview of the FDA. *Id.*, citing *Solvay Pharms. v. Ethex Corp.*, 2004 WL 742033, *2-*3 (D. Minn. March 30, 2004); *Solvay Pharms., Inc. v. Global Pharms*, 298 F. Supp.2d 880, 883-85 (D. Minn. 2004).

In *Axcan*, a branded drug manufacturer sued a generic manufacturer for false advertising and unfair competition under the Lanham Act, contending that the generic product was not truly a "generic equivalent." Although the generic manufacturer contended that primary jurisdiction was a defense to the claim, the court rejected the argument, reasoning that the branded manufacturer's claim was not that the defendants falsely implied that the drugs were equivalent within the scope of what the FDA permits, but rather whether the drugs truly were "generic equivalents" or "substitutes for" under the Lanham Act. *Id.*

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"Biannual Update Regarding…Preemption…"*—cont'd from page 10*

at *4; *see also Midlothian Labs., LLC v. Pamlab, LLC*, 509 F. Supp. 2d 1065, 1086 (M.D. Ala. 2007), reversed on reconsideration, 509 F. Supp. 2d 1095 (M.D. Ala. 2007) (holding that false advertising claims based on product equivalency representation are not preempted because the claim did not require the "interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA," and the owner was not alleging that the generic manufacturer's advertising implied FDA approval or endorsement based on FDA standards). Despite the conclusion reached in *Axcan*, preemption cases from outside the advertising context teach that the FDA's determination of issues within its regulatory purview often should trump liability premised on a different conclusion.

Removal & Preemption

Preemption can be a strong defense against state law claims, but the defense can backfire if used in inappropriate circumstances—and removal based on the defense of federal preemption almost inevitably backfires. In both *Von Essen v. C.R. Bard, Inc.*, 2007 WL 32751498 (D.R.I. Nov. 6, 2007) and *DeAngelo-Shuayto v. Organon USA, Inc.*, 2007 Wl 4365311 (D.N.J. Dec. 12, 2007), the defendants removed and then resisted remand motions by arguing that federal preemption issues gave rise to federal question jurisdiction. According to the defendants' arguments, the plaintiffs' prayers for punitive damages necessarily included a determination of whether the defendant knowingly withheld information about the safety of the device from the FDA. *See, e.g.*, *DeAngelo-Shuayto*, 2007 WL 4365311, *6. This, the defendants argued, implicated a "fraud on the FDA claim" that necessarily implicated the holding and analysis of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001), and transformed the claims into ones inherently federal in character. *Id.*, *see also Von Essen*, 2007 WL 3275148, *1. Both courts rejected this argument and remanded the cases on the ground that the mere presence of a federal issue did not operate "as a password opening federal courts to any state action embracing a point of federal law." *Von Essen*, 2007 WL 3275148, *2 (quoting *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 314 (2005)).

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