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Client Alert **Product Liability Law**

Federal Preemption in the Wake of Albrecht: The U.S. Supreme Court Unexpectedly Levels the Playing Field

Since the U.S. Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), preemption arguments in failure-to-warn pharmaceutical products liability cases have often focused on demonstrating that there was "clear evidence" that the FDA either rejected or would have rejected the proposed labeling change advanced by plaintiffs. Plaintiffs would oppose such preemption motions, arguing that the manufacturer could have updated the product label, without the FDA's approval, using the Changes Being Effected ("CBE") regulation. *See* 21 C.F.R. §314.70(c)(6)(iii)(A)(permitting "[c]hanges in the labeling to reflect newly acquired information . . . [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling . . . ."). Naturally, litigants had different views over how one established "clear evidence" for purposes of preemption. In *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 852 F.3d 268 (3d Cir. 2017), the Third Circuit further complicated the question when it ruled that the question of whether "clear evidence" existed was one of fact for the jury to decide.

In May 2019, the U.S. Supreme Court in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019) considered the Third Circuit's opinion, and made two major preemption rulings, one of which has already altered the course of preemption motions. First, the *Albrecht* Court clarified that "clear evidence" was "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would

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not approve a change to the drug's label to include that warning." *Id.* at 1672. Second, the *Albrecht* Court held that the issue of whether state law failure-to-warn claims were preempted by federal law was a question of law to be decided by the court, and not a question of fact to be decided by a jury. *Id.* at 1679-80.

It is this second ruling that has had a significant impact on preemption motions. For example, some manufacturers have recently argued successfully that even before a court reaches the question of whether there was "clear evidence" that the FDA would not have approved the label change, plaintiff's claims were preempted because there was no "newly acquired information" establishing a "causal association" between the drug at issue and plaintiff's alleged injury that could have justified using the CBE regulation to update the product label in the first place. Under the CBE regulations, "newly acquired information" includes "data, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type of greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). In the wake of *Albrecht*, courts appear more receptive to this argument.

The courts in each of the cases discussed below conducted an extensive analysis of the medical and scientific literature to analyze whether there was "newly acquired information" to justify the submission of a CBE, and in each case, the court concluded that plaintiffs presented nothing "new" to justify using the CBE regulation to update the label. As a result, the courts determined that plaintiffs' state law claims were preempted by federal law.

1. *McGrath v. Bayer Healthcare Pharms., Inc.*, 393 F. Supp. 3d 161 (E.D.N.Y. 2019)

In *McGrath*, plaintiff asserted failure-to-warn strict liability and negligence claims relating to injuries allegedly sustained from exposure to Magnevist, a contrast agent containing gadolinium administered to improve the quality of MRIs. Plaintiff alleged that she was never warned about the risks of gadolinium retention in patients with normal renal function or advised of alternative treatment options. As a result of her exposure to Magnevist, plaintiff alleged that the gadolinium caused "fibrosis in organs, bone, and skin" and "muscle pain, muscle weakness, brain fog and other injuries." *Id*. at 164-65. Bayer moved to dismiss the complaint arguing, among other things, that plaintiff's failure-to-warn claims were preempted because it would have been impossible to

include the warning advanced by plaintiff using the CBE regulation. *Id*. at 166-67. In reviewing the parties' arguments, the court determined that plaintiff's allegations did not state a claim because at the time plaintiff was exposed to gadolinium there was no "new" information demonstrating a "causal association" between Magnevist and a "clinically significant adverse reaction." *Id*. at 168. In so holding, the court reviewed the data available at the time the FDA approved Magnevist in 1988, and multiple subsequent reports and studies, and found that they did not support plaintiff's position. Because there was no basis for Bayer to unilaterally amend the warning under the CBE regulation, the court further determined that it was not required to consider whether there was clear evidence the FDA would not have approved a change to the label. *Id*. at 170-71. The court noted that in *Albrecht*, the "medical evidence revealed a reasonable, if not compelling, causal association – the kind of causal association the FDA contemplated before a drug company could unilaterally amend a warning under the CBE regulation", but that such a causal connection was not present here. *Id*. at 171.

2. *Roberto v. Boehringer Ingelheim Pharms, Inc.*, 2019 Conn. Super. LEXIS 2525 (Sept. 11, 2019).

Roberto presented a similar scenario. There, plaintiff asserted product liability claims against Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") based on personal injuries allegedly caused by the prescription medication Pradaxa, an anticoagulant designed to prevent strokes in patients with atrial fibrillation. *Id*. at *2. Plaintiff alleged that the Pradaxa label did not adequately warn about bleeding risks. *Id*. Plaintiff also alleged that the Pradaxa label should have included a warning that patients with a history of gastroesophageal reflux disease ("GERD") have an increased risk of bleeding on Pradaxa. *Id*. at *12-13. The case proceeded to trial where the jury returned a verdict in favor of plaintiff. The parties filed several post-trial motions, including BI's motion for judgment notwithstanding the verdict, which among other things, argued that plaintiff's failure to warn claims were preempted by federal law. *Id*. at *3.

Specifically, BI argued that between the launch of Pradaxa in October 2010 and the date of plaintiff's injury in January 2014, there was "no relevant 'newly acquired information' about Pradaxa that, under federal law, would allow them to change the Pradaxa label." *Id*. at *31. The court agreed. Relying on *Albrecht*, the court first determined that the court, and not a jury, should decide the issue of whether there existed newly acquired information. *Id*. at *37-38. In addition, the court noted that studies published after plaintiff's alleged injury were not relevant and could not constitute newly acquired information. *Id*. at *41-42.

Thereafter, the court extensively reviewed the various studies and articles that plaintiff relied on to argue that the Pradaxa label should have informed physicians that there was a therapeutic range of Pradaxa blood plasma concentration that physicians should monitor to insure that patients stayed within the therapeutic range to minimize the risk of bleeding events. *Id*. at *42-43. After conducting such review, the court determined that there was no newly acquired information that would have allowed BI to change the Pradaxa label with regard to blood monitoring or Pradaxa blood concentrations and, therefore, plaintiff's claims were preempted. *Id*. at *63-64. The court, however, determined that plaintiff's GERD claim was not preempted because, based on the record before the court, it was unclear whether the defendants submitted the European Pradaxa label, which contained warnings about GERD, to the FDA. *Id*. at *64-66. As a result, the court determined that plaintiff's GERD claim was not preempted because "[i]t is not clear that the defendants 'fully informed the FDA of the justifications for the GERD warning required by state law . . .' or that the FDA actually 'informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning.'" *Id*. at *72-73.

3. *Rosemary Lawson*, San Francisco Superior Court No. CGC-17-559611 (Nov. 8, 2019).

Roberto informed the result in *Lawson*. In *Lawson*, plaintiff asserted claims for strict liability failure to warn, negligent failure to warn, negligent misrepresentation, fraud and intentional misrepresentation, and punitive damages against BI based on her use of Pradaxa. In support of her claims, plaintiff alleged that the elevated levels of Pradaxa concentration in her blood caused her brain bleed and that her elevated levels of Pradaxa were due to her mild renal impairment, use of amiodarone, her age, and female gender. Plaintiff alleged that the warnings were deficient because BI failed to adequately warn prescribing physicians: "(1) that amiodarone, a P-gp inhibitor, increases exposure and bleeding risk; (2) that patients with mild to moderate renal impairment have a higher risk of bleeding; (3) that the female gender has an impact on plasma levels; (4) that there is a risk of bleeding with Pradaxa in elderly patients; and (5) of the impact plasma concentrations can have on bleeding risks, and as a result, the label should warn physicians about the need to monitor plasma concentrations to confirm that patients concentrations are not 'excessive,' 'too much,' or beyond the 'therapeutic range.'"

In support of its motion for summary judgment, BI argued that there was no "newly acquired information" about Pradaxa between its approval in October 2010 and March 14, 2016, (the date of plaintiff's brain bleed) that would have permitted BI to change the Pradaxa label. As a result, BI argued that plaintiff could not satisfy her burden under the first prong of the preemption analysis and, therefore, her state law claims were barred under federal law.

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In reviewing plaintiff's evidence, the court determined that plaintiff failed to satisfy her burden of demonstrating "newly acquired information". With regard to plaintiff's claims relating to blood-plasma concentration and monitoring, the court determined that since its inception, the Pradaxa label discussed the impact of Pradaxa plasma concentrations on bleeding risks, which information was submitted to the FDA before approval of Pradaxa's initial label. Further, the court rejected plaintiff's supporting evidence as being "newly acquired information". The court characterized the evidence as: "(1) conditional and/or preliminary, without the sufficient degree of scientific validity required to constitute newly acquired information, (2) does not present any new or different risk, and/or (3) post-date Plaintiff's 2016 injury."

Conclusion

These three post-*Albrecht* decisions demonstrate the potential positive impact that heightened judicial involvement can have on questions of preemption. The opinions each reflect the court's detailed and thoughtful review and analysis of scientific and medical literature pertinent to whether the manufacturer had "newly acquired information" of a causal association between the medication and the adverse event that could have justified using the CBE regulation to update the product label with new warnings. Whether these decisions reflect a trend remains to be seen, but they are a good sign that the *Albrecht* decision has had a positive impact on defense motions to preempt failure to warn claims.

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