

Product Liability

EXECUTIVE SUMMARY

This month, the U.S. Supreme Court will hear oral arguments in *Wyeth v. Levine*, a preemption case involving prescription medication labeling that some regard as the most significant business case this term. The case will greatly impact product liability practices and could invite new federal legislation. In addition, the growing popularity of aggregated proceedings in product cases has led the plaintiffs and defense bar to analyze the pros and cons of multidistrict litigation and Judicial Council Coordinated Proceedings.

Our panel of experts discusses these issues, as well as the potential barriers to court access created by the cost of litigating product cases, and general strategies for managing litigation costs. They are David DiMeglio and Peter Larson of Jones Day; Pamela Yates of Kaye Scholer; Scott Nealey of Lieff Cabraser Heimann & Bernstein; Erin Bosman of Morrison & Foerster; and Alicia Donahue and Frank Kelly of Shook, Hardy & Bacon. The roundtable was moderated by freelance writer Bernice Yeung, and reported for Barkley Court Reporters by Krishanna DeRita.

MODERATOR: What are the potential ramifications of *Wyeth v. Levine*?

YATES: This is a preemption case that is related to the labeling of a prescription medication, and the potential ramifications are significant. The litigation stems from the warnings surrounding the medication's method of administration. *Levine's* position is that the more dangerous form of administration should have been more specifically warned against or contraindicated. *Wyeth's* response is that the Federal Drug Administration (FDA) controls prescription medication labeling.

One key issue is the change-being-effected (CBE) provision within the Food Drug and Cosmetic Act (FDCA), which permits a medication manufacturer to change product labeling under certain circumstances. *Levine* argues that the state law, failure to warn, is not inconsistent with the federal law, FDCA, governing prescription medication labeling since the ultimate goal is consumer protection. The defense argued that the limited circumstances for CBE do not apply in this case, and that the state law and FDCA are at odds, thereby creating implied preemption since it's physically impossible to comply with state and federal law simultaneously, and the state law

stands as an obstacle to the accomplishment of the federal law.

Given the U.S. Supreme Court's *Riegel v. Medtronic* opinion from February, which found express preemption in a class-three medical device based on the pre-market approved process, one might think that the Court would follow the same precedent here. If it does find preemption, I anticipate legislation to be introduced on this subject, so I don't believe that pharmaceutical product liability cases will disappear.

BOSMAN: Defense attorneys are bringing more motions to dismiss based on express or implied preemption. Despite the current popularity of *Riegel*, standard of care preemption is not limited to medical devices. In *Montalvo v. Spirit Airlines*, the Ninth Circuit held that the Federal Aviation Act of 1958 preempts the entire field of aviation safety through implied field preemption. The courts' analysis in *Riegel* and *Montalvo* indicates that where a federal agency has rigorously evaluated the safety and effectiveness of a product or regulation, it amounts to a federal safety review and additional state laws or requirements will be preempted.

NEALEY: There are major public policy implica-

tions of preemption that courts are not, in normal course, structured to deal with. They don't hold hearings, invite public participation, or do independent fact-finding. This cries out for this issue—where, as here, there is no legislative authority for preemption—to be left to Congress.

KELLY: Those are the same arguments that the California Supreme Court used in *Ramirez v. Schering-Plough*, which found that the warning on baby aspirin didn't also need to be issued in Spanish. The court pointed out the same things: it's a complex issue, there are competing policy considerations and there's fact-finding and research that should drive the decisions. All of which led the California Supreme Court to leave things to the regulators. When dealing with complex issues and new science, the deference the courts give to the regulatory agencies seems appropriate. So those are some good reasons for arguing that preemption is appropriate in this case.

NEALEY: Yet the editors of the *New England Journal of Medicine*, former heads of the FDA, 47 state attorney generals and every state legislature filed amicus briefs against preemption because we aren't talking about agency expertise here; we're

ROUNDTABLE

talking politics. The implied preemption doctrine should be limited to when Congress has granted authority, and careful consideration of a specific issue by the agency can be shown. There was never an adjudicative procedure on the method of drug injection that occurred in *Wyeth*; the FDA never considered the issue or held hearings on it.

YATES: But the FDA, on numerous occasions, did re-evaluate the labeling. So this was not politics; it was science. Can you permit a jury in Vermont to second-guess the FDA? A jury that might reach a different conclusion in California or New York? From my perspective, it was an adjudicated issue. The information and the risks were known to the FDA. It was presented to medical experts, but you now have a jury saying, "That's not good enough."

LARSON: Denying preemption in *Wyeth* would interfere with the FDA's expertise and experience in approving drugs. Every drug has risks and benefits and Congress has determined that the FDA must decide whether, on balance, the benefits that a drug affords outweighs the risks. I don't think we want this to be determined in a case-by-case basis by juries. In most instances where this issue comes up in a jury trial, it will involve a dramatic and perhaps tragic example, as is the case in *Wyeth*. In litigation, it's not going to be the balanced, across-the-spectrum application of the drug, nor will litigation permit a thorough analysis of the drug and its benefits. The FDA is in a better position to make those kinds of determinations than juries are. At bottom, *Wyeth* is the type of case that the FDA has stated should be preempted: A state law claim that challenges FDA-approved labeling after the agency had been informed of the health risk, and which was based on agency expertise in determining whether additional or different warnings were needed.

DiMEGLIO: The Supreme Court's decision will certainly have an impact on the scope and interpretation of CBE regulations. The decision of the Vermont Supreme Court, which declined to find preemption in *Wyeth*, was premised largely upon the court's finding that FDA's labeling requirements are minimal standards and that *Wyeth* could have strengthened the labeling for the prescription drug at issue without prior FDA approval under CBE regulations.

In *Wyeth*, however, the side effect at issue was not only known to the FDA, but was actually

warned about in the drug's labeling. This should make the CBE regulation inapplicable; the CBE regulation is intended to cover only newly discovered side effects. The recent revision to the CBE regulation codifies FDA's longstanding policy to allow CBE changes only when a sponsor has newly discovered and scientifically significant evidence not previously submitted to the FDA. The CBE regulation has no application to the risks of the drug that were already known and considered by the FDA. The FDA approval process would be rendered meaningless if, after approval, a manufacturer's label still exposed the manufacturer to inconsistent tort liability under existing state laws because the label didn't include information that the FDA already determined should not be included.

BOSMAN: While preemption does not eliminate a plaintiff's ability to bring a claim, it does limit the claims that can be brought. Reigel clearly states that a state may provide a damages remedy for state claims that are parallel to federal requirements. However, parallel claims will probably come to really mean manufacturing defect claims and provable violations of federal regulations. If preemption is not found in *Wyeth*, pharmaceutical companies will be expected to comply with 50 different state requirements, and manufacturers would face an unending stream of litigation based on different standards of care.

NEALEY: But if you don't have a failure-to-warn cause of action, and if preemption were to be found in these areas, it basically closes the courthouse doors. Most product liability litigation regarding drugs is not related to a manufacturing defect. Theoretically, there is a strict liability cause of action, but given the learned intermediary rule, this claim is basically it.

I also disagree with the argument that CBE regulations are a "ceiling." That the FDA was aware of the risks of some drug administration methods, and then decided against including a warning on the label is not supported by the record in *Wyeth*. Since the change in administration, the position taken on these issues since the 1970s is simply different than the current position being taken by the FDA, which is that CBE is a ceiling, not a floor.

DONAHUE: Scott [Nealey] is arguing that the FDA is politically motivated, but looking at preemption cases in general—and this predates the Bush administration—we are seeing federal agencies



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ROUNDTABLE

weigh in more frequently on cases that may interpret their regulations, and probably rightfully so. So we can't just file that away as political motivation. We have to also respect the fact that these agencies have an interest in these cases because they are the authority on these matters. There's another implied preemption case pending before the Supreme Court, a tobacco case, *Altria v. Good*, where the position of the Federal Trade Commission (FTC) is part of the briefing. From a plaintiff's perspective it may seem unfortunate that these agencies, in certain cases, have positions in alignment with the defense position, but we can't just assume that it's a politically motivated move. We are going to continue to see more of the agency perspective in amicus briefing no matter who is in office.

BOSMAN: For attorneys who represent pharmaceutical and medical device manufacturers, the effect of preemption in *Wyeth* is that we'll see claims brought against defendants that generally should have been named in the first place—the doctors. Many of the personal injury cases regarding pharmaceutical drugs and medical devices are truly medical malpractice cases. Instead of naming the doctor as a defendant, the plaintiffs bar typically goes after the deep pockets by only naming the manufacturers as defendants.

MODERATOR: What has caused and what are the effects of the current popularity of aggregating claims at the state and federal level?

DIMEGLIO: The popularity of multidistrict litigation (MDL) and coordinated proceedings in product liability actions is likely due to a number of factors, including the courts' and attorneys' increased experience with the mechanisms and procedures for aggregate litigation, as well as perceived efficiencies in case management and discovery. Mass and instant communication have also allowed plaintiffs and their counsel from across the country to come together to pool their cases more easily. This issue was recently analyzed in an article by my colleagues, Mark Herrmann and Pearson Bownas, who found that the MDL panel granted 89 percent of the transfer motions filed in product liability cases between 2000 and mid-August 2006.

From the defense perspective, mass tort proceedings often include weaker cases that might not have survived scrutiny at the filing stage as a stand-alone case—the plaintiffs apparently hope

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that scrutiny can be avoided through streamlined discovery processes and that they'll gain some settlement leverage by increasing the total number of cases a defendant faces. The inclusion of multiple defendants with competing interests also can hamper one defendant's ability to narrow the issues and dispose of the litigation quickly. For these reasons, defendants are taking a more considered approach in determining whether aggregate litigation makes sense in a case.

YATES: The efficiencies for a defendant, including coordinated discovery—company employees are not exposed to multiple depositions in different jurisdictions—is balanced against the reality that when you have a consolidated proceeding or MDL, weaker cases get thrown into the mix because plaintiff law firms realize that that adds to their inventory for settlement purposes.

In terms of what has increased the popularity of these aggregated claims, the mechanisms for MDL and consolidated proceedings have been in place for a long time so it seems as if both plaintiffs and defendants have come to terms with the benefits and are taking advantage of these mechanisms more often. I think skepticism has declined, particularly from the plaintiff side.

BOSMAN: In certain situations, such as litigation involving a mass disaster, defendants would agree that an MDL is useful. But in individual injury allegations, defense counsel are beginning to push back on requests to consolidate through MDL. For instance, all of the defendants opposed centralization in the shoulder pain pump products liability litigation. The Judicial Panel on Multidistrict Litigation (JPML) denied the MDL because the various individual issues overwhelmed any efficiencies that might be gained by centralization. The JPML also noted that many of the defendants were only sued in a minority of the actions.

ROUNDTABLE

From the defense perspective, denying this type of request for centralization results in fewer claims being filed by plaintiffs bar because they will have to individually prosecute each case.

KELLY: I agree that there's a tension on this issue from the defense side. There's a certain volume where the benefits seem to start outweighing the downsides. But it seems that there has been a number of plaintiffs firms that have embraced aggregated cases. Lief Cabraser wrote the book on it, but now, a number of what used to be called lone ranger plaintiffs firms, like Girardi & Keese and Robinson, Calcagnie & Robinson have embraced aggregated cases and have created a structure internally in their firms to handle these cases, whereas ten years ago, these firms were out on their own and primarily taking individual cases.

NEALEY: That's true. But it is also becoming a case-by-case question for plaintiffs. There's one particular product defect mass tort I'm working on where we actually don't want an MDL because we are in a position to quickly litigate the cases individually. That said, the judicial system can be well served by coordination. Recently, in the Bextra/Celebrex case, we've been able to put together good coordination with state courts, which keeps transaction costs down all around. However, we hear frequently from the plaintiffs' side that MDLs are sometimes used to slow everything down. If that trend continues, you'll see the good plaintiffs firms start to opt out of MDLs and coordinated procedures and find a way to get these cases into state courts.

LARSON: I have seen a large increase in MDLs and the state counterpart, Judicial Council Coordinated Proceedings. Judges increasingly are looking for opportunities to gain control over ever-expanding dockets. This has led to coordination not only under the specific rules, but also to less formal aggregation of multiple cases involving one or two kinds of similar injury, even if the cases don't have many or any additional significant similarities. When such proceedings are coordinated, it can result in an unwieldy mass of cases, many of which are not meritorious. We then have to go through a cost-benefit analysis, which actually works to the detriment of both meritorious plaintiffs and defendants, because this process of adding dubious cases to the docket delays settlement of meritorious cases. Defendants are dealing with this more today than ever before.

KELLY: On the plus side, one advantage for the defense is that eventually, you can always try the case if you feel it's necessary. There isn't the same concern that there might be in the class action setting where you could get res judicata and collateral estoppel findings. So the potential of a bad result isn't that great if you voluntarily participate in coordinated proceedings and MDLs.

DONAHUE: The American Law Institute (ALI) has been spending lot of time looking at these issues and coming up with some recommendations and guidelines for what aggregate litigation is, what cases it should involve and how it should be handled. We are certainly going to continue to see it, so both sides benefit from coming up with a group of policies and procedures to keep things moving forward. And it has to be a collaborative process. Once you are in the actual litigation itself, you are there to advocate for your client. But initially it is to the benefit of all parties to get the best procedures in place to govern aggregate litigation.

LARSON: It is important to ensure that the coordination process is, in fact, a collaborative process, and that those mechanisms are arrived at jointly, rather than having a circumstance where one side gains a significant tactical advantage by the way the program is put together.

MODERATOR: What role can the courts play in controlling the cost of product liability litigation generally and to preserve access?

NEALEY: One issue we are concerned about is access to courts. In cases where somebody was clearly injured, but their medical bills are \$50,000 or \$100,000, the system is so expensive that it can affect their access to courts. From the defense side, what are your thoughts on cases where the damages are not particularly high?

KELLY: Those cases have dropped out of the system. I grew up on cases like that, and nowadays, you either have catastrophic injury cases or wrongful death cases. But that midrange case—the plaintiffs bar doesn't seem to be filing them. These are the cases that the younger attorneys need in order to develop their trial skills. It's a mystery to us on the defense side as to why they aren't being brought because the level of proof necessary to get a case to the jury in a product liability case in California isn't that high, although the defense that

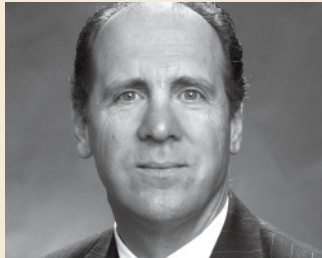


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ROUNDTABLE



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will be mounted will probably be stiff, and most of those cases are lost by plaintiffs. But 10 years ago, that didn't stop plaintiffs from filing them.

BOSMAN: When those types of cases are filed, we generally contact the plaintiffs attorney and ask for documentation so we can evaluate the injuries and the damages prior to spending time defending the action. However, the response from plaintiffs is usually silence. So it's interesting to hear Scott [Nealey] say that he is having a hard time with these cases because of the cost of taking them to court.

DIMEGLIO: This phenomenon probably goes hand-in-hand with what we are seeing with the increase in mass tort cases. The mass tort and catastrophic injury cases continue to get the headlines and the attention of the plaintiffs bar, but it's not that there aren't cases with lower damages on the plaintiffs' side; it's just that plaintiffs counsel have become more selective in what cases they bring. To Erin [Bosman's] point, it does behoove all parties for the attorneys in those middle-ground cases to engage in informal discussions with a real exchange of information that facilitates an early and more realistic resolution—including a sworn statement or mini-deposition of the plaintiff, signed releases for medical and other documents,

without waiting for formal discovery to begin.

DONAHUE: Whatever the economic damages are and whatever the liability issues are on either side, there's a value to evaluating the case at an early stage. And, in most instances, long before you are disclosing experts and getting into the big money, both sides have an incentive to work it out. The defense obviously is under an obligation to do certain things to be able to evaluate the case, and sometimes the plaintiffs bar considers these efforts to be an attempt at getting the plaintiff to spend a lot of money. In many cases, long before experts are retained, the parties should be able to talk about case value and settlement. As the defense, we are generally agreeable to that. Once experts are hired, there may be a higher dollar figure on the case from the plaintiffs' perspective because the parties are into a bigger expenditure than maybe was originally planned. The amount of economic damages from a defense perspective does not always dictate how expensive the trial is going to be, so it's not as though the damages always dictate the point at which a defendant is willing to discuss settlement. We need information on the case, factually and damages-wise.

LARSON: Defense counsel are very interested in determining as quickly and as inexpensively as possible what the true value of a case is, whether it's an individual case or a series of cases. It is often difficult, however, to come to that kind of an analysis early on between plaintiffs and defense lawyers, whether that's because of the nature of the discovery process or the inherent tension that comes from the adversarial process. It can be helped substantially when you are dealing with firms or lawyers with whom you have experience. Many judges are also quite good at bridging those differences early on.

BOSMAN: The other part of this question is: What role can the courts play in keeping litigation costs down? Plaintiffs frequently name defendants without making an effort to figure out which defendants' product was actually used. The plaintiffs counsel often pushes discovery forward without investigation and dismissal of the defendants whose product is not at issue. In pharmaceutical cases it is essential for plaintiffs counsel to obtain the medical and pharmacy records at the outset of litigation to ensure that product identification has been established and defendants whose drug

is not implicated are dismissed. This is crucial to keeping costs down.

LARSON: We do frequently find ourselves in a position where we are simply named because we are in that line of business, and then we incur the costs defending a client which ultimately shouldn't have been sued, or at least not yet. California has the *Doe* amendment process, which should allow for some discretion on the part of naming defendants in those kinds of cases.

KELLY: You can't have a discussion about the expense of bringing a product liability case without talking about discovery, and discovery left unchecked by the court can be very expensive because then there's no control, no direction, and no collaboration and it comes down to whether the parties can agree. If there's a party involved who isn't cooperative for whatever reason and the court doesn't step in, it's going to be expensive. There are benefits to both sides to encourage the courts to step in and modify or accelerate certain discovery so that substantial costs are remote and up-front costs are reduced.

YATES: What also seems to help keep costs down is the bellwether process, where you select a group of representative plaintiffs and work those up to trial. This not only helps you determine what a real case looks like, but also the potential exposure. We're seeing this process at the state court level and in MDLs and it at least defers some of the massive expense in the discovery process and helps set a template so that general expert work-up doesn't need to be redone.

NEALEY: Something that defendants sometimes ignore in a mass tort context is that when you have hundreds of cases, it gets expensive when it comes to plaintiff fact sheets or production of information, let alone a *Lone Pine* order. The more complex the process, the less responsive plaintiffs will be, which sets up an expensive compliance process. This doesn't benefit anyone—it ultimately increases the settlement costs. Fact sheets, or docket sheets work best if kept to key information. I'm also glad to hear that everyone has said that in lower-value cases, plaintiffs can be more proactive about working with defense counsel early on. That said, we have seen the costs of litigation limit some filings and leave people with legitimate claims unable to get representation in products cases. ■

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