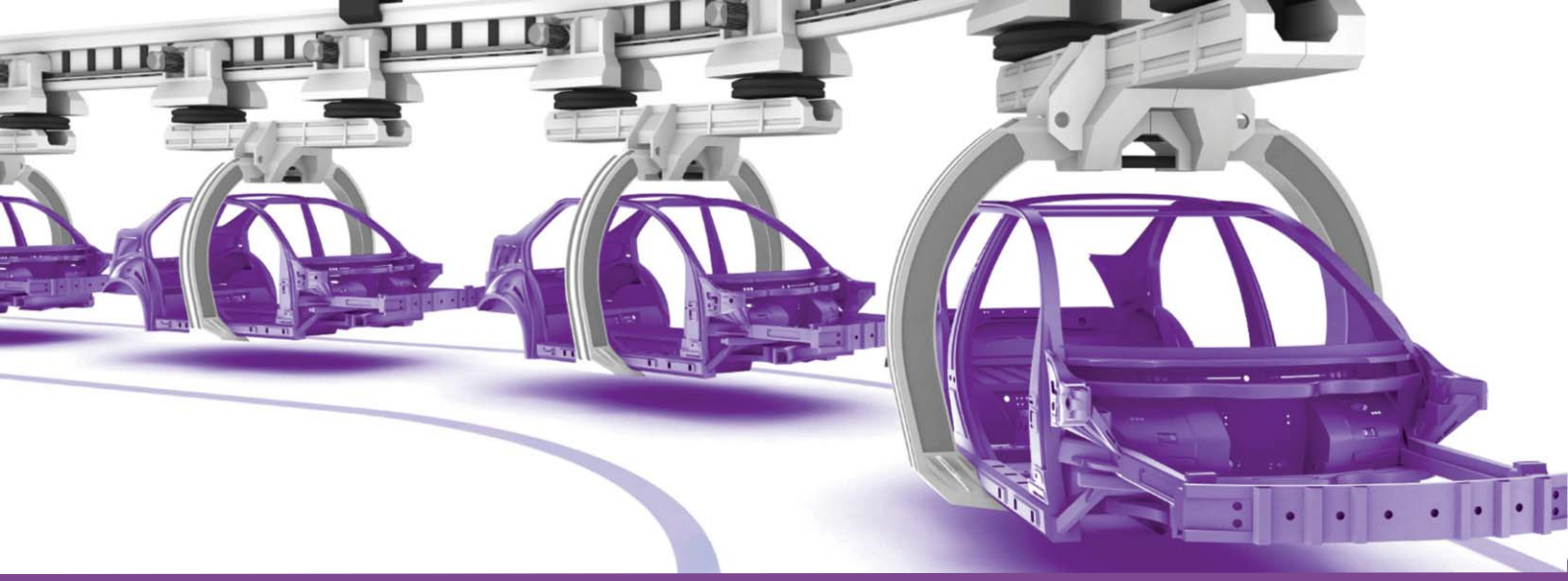

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The International Comparative Legal Guide to:

Product Liability 2012

10th Edition

A practical cross-border insight into product liability work

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The International Comparative Legal Guide to: Product Liability 2012

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EDITORIAL

Welcome to the tenth edition of *The International Comparative Legal Guide to: Product Liability*.

This guide provides corporate counsel and international practitioners with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

Ten general chapters. These are designed to provide readers with a comprehensive overview of key product liability issues, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 26 jurisdictions.

All chapters are written by leading product liability lawyers and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors Ian Dodds-Smith of Arnold & Porter (UK) LLP and Michael Spencer QC of Crown Office Chambers for their invaluable assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The International Comparative Legal Guide series is also available online at www.iclg.co.uk

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PREFACE

I'm delighted to have been asked to introduce the tenth edition of *The International Comparative Legal Guide to: Product Liability*.

The guide continues to be an invaluable source of information and comes this year with ten very interesting and varied general chapters as well as the extremely informative country question and answer section, covering 26 jurisdictions.

I make constant reference to the guide for matters concerning product liability globally; I'm also aware that my colleagues in Europe and across the world continue to rely on the guide as a first port of call for information on product liability and helps inform their advice.

The area of product liability continues to provoke interest from all areas, which I hope will necessitate future editions of this excellent guide.

Tom Spencer
Counsel
Litigation, Product Safety, UK
GlaxoSmithKline Plc.

Generic Pharmaceutical Liability — Challenges and Changes

Jones, Walker, Waechter, Poitevent, Carrère Denègre L.L.P.

Steven F. Casey

Generic pharmaceutical manufacturers were rewarded for their patience in the summer of 2011. They had been waiting anxiously to see how the Supreme Court of the United States would rule in two consolidated cases which presented the question of whether federal law preempts state law product liability claims against generic drug manufacturers. The Court ruled in their favour, finding that the Food & Drug Administration (FDA) labeling regulations preempt state law failure to warn claims. The Court's ruling provides generic manufacturers with significant protection against failure to warn cases, even as practitioners still work to implement the decision at the trial court level.

The Growth of the Generic Drug Market

In 1984, the Food, Drug and Cosmetic Act was amended by the so-called Hatch-Waxman Amendment to allow for the post-patent manufacture of established drugs by new manufacturers who only had to establish a few limited items in order to have an Abbreviated New Drug Application (ANDA) approved by the FDA. The policy behind allowing such generic forms of previously approved drugs to be manufactured was to allow lower cost drugs to come to market in the United States. Essentially, once an innovator drug's patent expired, a generic manufacturer could obtain approval from the FDA to manufacture and sell the drug by demonstrating that its drug was bioequivalent and that the labeling proposed by the new manufacturer was the same as the label used by the brand name manufacturer. In fact, the generic manufacturer, in its ANDA, was obliged to include a side-by-side comparison of the two labels to demonstrate that its label was the same as the old label.

In contrast, a manufacturer which develops or innovates a new drug must demonstrate, through a rigid and lengthy process, including scientific studies that it and perhaps others have conducted, that the drug is both safe and effective. A generic drug only comes to the market years after an innovator company has made such a demonstration, during which time the drug has been on the market and many, many doses of it have been administered, resulting in significant experience as to its safety and efficacy even after approval by the FDA.

The reasoning behind the generic drug industry concept is that any further costly research regarding the safety and efficacy of a drug that had been approved by the FDA years earlier was unnecessary and duplicative. Theoretically, a drug coming off patent has been on the market long enough so that its relative safety for use has been effectively established. The idea, of course, was that without the cost of the studies performed by the original innovator, or brand manufacturer, the generic manufacturers could sell the drug to the market at a much lower cost to consumers.

Failure to Warn Theories

As long as drugs have existed, there have been people who experienced, or claimed to experience, adverse reactions after taking them. Adverse reactions give rise to lawsuits. Plaintiffs' theories of liability against drug manufacturers, brand name and generic alike, almost always focus on some variation of a failure to warn theory. Plaintiffs typically assert that there is scientific evidence available that requires the manufacturer to provide further, or more stringent, warnings about its use or possible side effects. Both brand name and generic manufacturers have argued that failure to warn claims are preempted by federal law.

Failure to Warn Against Innovator Drug Manufacturers

Brand name drug manufacturers tested their federal preemption defence in *Wyeth v. Levine*, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). The Levine case was filed by a plaintiff who alleged that she suffered an adverse reaction after receiving an inter-arterial injection of Phenergan®. The Phenergan® label warned against inadvertent intra-arterial injections. The plaintiff argued that the warning was not strong enough because it failed to warn of the specific risks associated with inadvertent intra-arterial injections of Phenergan®. The plaintiff also argued that intra-venous injections of Phenergan® should have been contraindicated. Wyeth argued that the plaintiff's claims were preempted by federal law because the FDA mandates the language to be used on drug labels and in drug warnings. Wyeth contended that such requirement made it impossible for Wyeth to comply with both the FDA's labeling requirements and state common law relating to the adequacy of warnings.

The issue was litigated to the Supreme Court, which found that federal law did not preempt state law failure to warn claims against brand name drug manufacturers. The Court explained that the FDA's "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon the filing of a supplemental application with the FDA and it need not wait for FDA approval. The Court went on to explain that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market."

Failure to Warn Theories Against Generic Drug Manufacturers

Generic manufacturers have typically responded to failure to warn cases by pointing out the clear requirement, imposed by the FDA, that in order to get approval to market a drug, a generic company must demonstrate that its label is the same as that of the brand manufacturer of that drug. The logical extension of that argument has been that, if generics do comply with that rule, then they should be free from attacks over the label; in other words, that the federal requirements regarding labeling preempt state law failure to warn claims. Notably, the FDA's CBE regulations do not apply to generic manufacturers.

The generic manufacturers tested their federal preemption defence in two cases that were consolidated for appeal to the Supreme Court of the United States: *Demahy v. Actavis and Mensing v. Wyeth*. The issue presented in these cases was whether state law failure to warn claims against generic pharmaceutical manufacturers are preempted by federal law. On June 23, 2011, the U.S. Supreme Court released its highly anticipated ruling in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 180 L. Ed. 2d 580, 2011 U. S. LEXIS 4793 (2011). In a 5-4 opinion, the Court held that state law failure to warn claims against generic drug manufacturers are preempted by state law.

In *Demahy v. Actavis, Inc*., 593 F.3d 428 (5th Cir. 2010), and *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), the United States Courts of Appeal for the Fifth and Eighth Circuits, respectively, had held that federal law did not preempt state law claims. The United States Supreme Court granted petitions for *writs of certiorari* in both cases and entertained oral argument on March 30, 2011. The high court's formal opinion followed a few months thereafter.

In order to fully examine the significant impact on the generic pharmaceutical industry and product liability litigation concerning it brought about by this decision, a review of the facts of each of the two cases is helpful.

Demahy (5th Circuit)

In *Demahy*, the plaintiff's physician prescribed the drug Reglan to treat gastroesophageal reflux. The plaintiff's pharmacist filled the prescription with the generic form of the drug, metoclopramide, that had been manufactured by Actavis. Although it was well known that prolonged use of the drug is associated with a movement disorder, tardive dyskinesia, Ms. Demahy took metoclopramide for four years. She developed symptoms of tardive dyskinesia and sued Actavis, alleging that it failed to adequately warn her of the risks of the drug.

Actavis argued that Demahy's state law claims of failure to warn was preempted by federal law.

The Fifth Circuit noted early in the *Demahy* opinion that the FDA has required the risks of tardive dyskinesia were to be disclosed in metoclopramide labeling since 1985. It also mentioned a February 2009 labeling revision—widely known in the industry as a "black box" warning—that spoke of the dangers of prolonged use of the drug, but omitted the fact that the black box language added very little of substance.

In the *Demahy* case, Judge Patrick Higginbotham of the Fifth Circuit wrote that there was insufficient statutory evidence to conclude that Congress intended to provide preemption protection to *generic* manufacturers. In so holding, the Fifth Circuit followed what it considered to be the foreshadowing decision of the U.S. Supreme Court in *Wyeth v. Levine,* 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). In *Levine*, the U.S. Supreme Court held that FDA labeling requirements did not preempt state law claims against *brand name* manufacturers.

In analysing the statutory and regulatory framework that controls the generic industry, the Fifth Circuit first found that the FDA regulation that required a generic drug's label to be "the same as" its brand name counterpart only applies to the *initial* labeling described in the manufacturer's ANDA. It reached this conclusion because the regulations are "silent as to the manufacturer's obligations after the ANDA is granted." *Demahy*, 593 F.3rd at 436, citing *Bartlett v. Mutual Pharm. Co*, 659 F. Supp. 279 (D. N. H. 2009), 2009 U. S. Dist. LEXIS 90528, 2009 WL 3126305, at *12 (quoting *Stacel*, 620 F. Supp. 2d at 907). In reaching this conclusion, the Fifth Circuit ignored the fact that the FDA has routinely taken the position that a generic's label must *always* be the same as that of the brand. This has been the FDA's practice, even though it withdrew an amicus brief saying so which it had filed in another significant preemption case. This backtracking of the FDA on this official position was notable to the *Demahy* court.

After concluding that there was nothing in the FDA regulations saying that generics do not have an obligation to update their label, the Fifth Circuit listed several methods available to brand name drug manufacturers to make changes in labeling, and eventually indicated that it considered that these same methods were available to generic manufacturers as well.

The first way that labeling changes might be made, according to Judge Higginbotham, was the use of a CBE mode of operation. This allows a manufacturer to go ahead and change its label—while asking the FDA to approve that change—before the FDA gives final approval for such.

The Fifth Circuit also referenced the "prior approval" method, whereby a manufacturer requests permission for a labeling change and waits for approval from the FDA before implementing it.

The appellate court also mentioned the use of "Dear Doctor" letters as another method of changing instructions for use or warnings in a drug's labeling.

In FDA regulations for each of those 3 methods, there is no specific language applying them to generics. The Fifth Circuit stated, in no uncertain terms, that if Congress had wanted these methods of changing warnings not to apply to generics, it could have said so. The converse argument seemed just as strong of course—if Congress had wanted these methods to apply to generics, Congress could have specifically pointed that out as well. One could almost flip a coin to determine what side of that argument one adheres to.

Regardless of the fact that the generic manufacturing industry and the FDA had hammered out a fairly standard practice of dealing with labeling issues—even if those standard practices weren't always entirely consistent with the wording found in the statutes and regulations—the Fifth Circuit in *Demahy* affirmed the basic premise that a drug manufacturer remains primarily responsible for maintaining its labeling consistent with principles of safety and efficacy in the use of its products.

Mensing (8th Circuit)

In *Mensing*, the United States Court of Appeals for the Eighth Circuit reached the same conclusion that was reached by the Fifth Circuit in *Demahy*, and stated that: "[f]ar from prohibiting [generic drug manufacturers] from taking steps to warn their customers of new safety hazards, federal law requires such action." 588 F.3d at 614.

Interestingly, Ms. Mensing had taken the same drug—metoclopramide—as had Ms. Demahy, and she took it for the same length of time—4 years—even though the label indicated that it was only intended for short duration use, defined in the label as no longer than 12 weeks. The plaintiff's physician had prescribed the drug for another of its approved uses—the treatment of diabetic

gastroparesis. As in *Demahy*, the plaintiff in *Mensing* developed tardive dyskinesia, and filed suit against the manufacturers of the generic metoclopramide that she took, claiming that they had failed to adequately warn her of the risks of that particular side effect. Additionally, *Mensing* asserted that the defendants "promoted metoclopramide for long term use even though the FDA had approved the drug only for use for up to 12 weeks".

The parties to the *Mensing* case raised the same issues that were raised in *Demahy*. The Eighth Circuit declined to adopt the generic drug manufacturers' position on the CBE regulations, holding that even if the CBE rules were not available to generics, the prior approval method of effecting labeling changes was available.

The Eighth Circuit also rejected the defendants' preemption argument. In doing so, the Court noted that a legal presumption exists against preemption. The Court found that: "[t]he regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug." In fact, in response to the defendants' argument that generics are limited in how they are able to effect labeling changes under the FDA regulations, the court stated bluntly: "The generic defendants were not compelled to market metoclopramide. If they realised their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product."

Although perhaps not particularly important, a difference in *Demahy* and *Mensing* at the Circuit Court level existed on the issue of whether a generic drug label must be "the same as" that of the brand name drug only at the application process or during the lifetime of the drug. The Fifth Circuit repeatedly pointed out that the regulations only speak to the ANDA process, while the Eighth Circuit recognised that: "[t]he parties agree that generic labels must be substantively identical to the name brand label even after they enter the market."

Nonetheless, the initial appellate treatment of the arguments in *Demahy* and *Mensing* both concluded that state law claims against generic drug manufacturers were not preempted by federal law. Each opinion relied in part on the U.S. Supreme Court's ruling in *Wyeth v. Levine,* 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), which reached the same conclusion—rejecting preemption—in cases involving brand name drug manufacturers.

PLIVA, Inc. v. Mensing (Supreme Court of the United States)

A year after its decision in *Wyeth v. Levine*, the Supreme Court addressed the generic drug manufacturer's preemption argument in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 180 L. Ed. 2d 580, 2011 U. S. LEXIS 4793 (2011).

The Supreme Court found that a conflict between state and federal law existed, making it impossible for a manufacturer to comply with both state and federal law requirements. In such situations, state law must give way. The Supreme Court found that a conflict exists between state law failure to warn claims asserted in the *Mensing* case and the Hatch-Waxman amendments to the FDCA. Specifically, the Court found that, under the Hatch-Waxman amendments, a generic manufacturer seeking approval to produce a generic form of a brand name drug must show that the drug it wishes to produce is equivalent to an already-produced brand name drug and that the safety and efficacy labeling it proposes is the same as that already approved for the brand name drug. Therefore, the Court reasoned, the generic drug manufacturers could not comply with the Hatch-Waxman amendments and provide the strengthened warnings that the plaintiffs contended were required, because the generic manufacturers had no ability to change their labels.

In reaching this decision, the Court specifically rejected the Eighth Circuit's reasoning that the generic manufacturers could have satisfied the state law warning requirements by proposing label changes to the FDA. The Court explained that state law demanded a safer label, not communication between the manufacturer and the FDA. Therefore, even if the generic manufacturers had proposed label changes to the FDA, they could not have compelled the FDA to approve such changes. In such a circumstance, if the generic manufacturers' suggested label changes had not been approved, the generic manufacturers would still be in violation of state law.

The Supreme Court further noted that had the plaintiff taken Reglan rather than metoclopramide, her claims would not have been preempted. The Court acknowledged that, from the plaintiff's perspective, the finding of preemption in this case but not in *Wyeth v. Levine* makes little sense. However, the Court noted that Congress enacted meaningfully different statutory schemes to govern generic manufacturers than those enacted to govern brand name manufacturers. The Court concluded that those different statutes and regulations lead to different preemption results and noted that Congress and the FDA have the authority to change the law and regulations if they so desire. Until Congress or the FDA adopts such changes, plaintiffs will not be able to maintain state law failure to warn claims against the manufacturers of generic drugs.

Leaving no guesswork as to what the majority opinion meant, Justice Sotomayor, in dissent, said this: "a drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth.* If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue."

Id. at 2592.

Failure to Warn Claims After *Mensing*

It should be easy to conclude after the *Wyeth* and *Mensing* decisions that consumers who suffer adverse reactions after taking a generic drug are left without a legal remedy to compensate them for their injury. Certainly, Justice Sotomayor thought that to be the case. However, there are alternate theories of liability to which plaintiffs are resorting that could possibly compel a different result.

The primary alternate theory was first advanced in *Conte v. Wyeth, Inc*., 85 Cal. Rptr. 3d 299 (Cal. App. 2008). In that case, the plaintiff developed tardive dyskinesia after taking metoclopramide for almost four years. He sued Wyeth, the manufacturer of Reglan—the brand name version of metoclopramide—and three manufacturers of generic metoclopramide, alleging that the defendants should have known of a widespread tendency among physicians to misprescribe metoclopramide for periods longer than that called for in the labeling because the label allegedly understated the risks of extended treatment with metoclopramide. It was undisputed that the plaintiff only ingested generic metoclopramide, not Reglan. His claims against Wyeth were premised on misrepresentation in Wyeth's labeling of Reglan and in a monograph on Reglan it provided for the Physician's Desk Reference. The trial court entered summary judgment in favour of the defendants and the plaintiff appealed.

On appeal, the California Court of Appeals held that it is very likely that a prescription for Reglan written in reliance on Wyeth's product information would be filled with metoclopramide. Therefore, the Court reasoned, it was foreseeable that a physician might prescribe generic metoclopramide in reliance on Wyeth's representations about Reglan. Based on this logic, the California Court of Appeals reversed the trial court's entry of summary judgment and held that a brand name manufacturer could be held liable for its failure to

warn consumers of generic drugs of the adverse reactions they could suffer from ingesting a generic version of the brand name manufacturer's drug.

While this may seem to be an incredible result, remember that the FDA regulations impose a duty on the brand name manufacturer to provide an adequate label and to ensure that its warnings remain adequate as long as the drug is on the market. Generic manufacturers, on the other hand, must label their drugs with the exact language found on the brand name drug's label. Even so, a number of courts have rejected the reasoning of *Conte*. The Alabama Supreme Court has yet to weigh in on the *Conte* theory of liability, though the question is currently before it in a question certified by the United States District Court for the Middle District of Alabama, in *Wyeth, Inc. v. Danny Weeks.*

While *Conte* stood before the U.S. Supreme Court issued the *Mensing* decision, there has been a flurry of other attempts, thinly disguised as other legal "theories," by plaintiffs to circumvent *Mensing* and stay in court against generic manufacturers. Most of these efforts have been made in cases pending when *Mensing* was issued. Despite those efforts, the vast majority of courts before whom the issue has been squarely presented, have dismissed those pending failure to warn claims against generics, understanding the clear language of the controlling decision to mandate such.

Examples of plaintiff attempts to distinguish other claims from those disposed of in *Mensing* include:

Mensing v. Wyeth, Inc., No. 08-3850, (8th Cir., Sept. 29, 2011), where the court denied Mensing's motion for leave to file supplemental briefing and affirming the dismissal of her claims by the district court.

Smith v. Wyeth, 2011 WL 43893211 (6th Cir., Sept. 22, 2011), rejecting the theory that a generic manufacturer had a duty to communicate a label directly to a physician.

Metz v. Wyeth, LLC, No. 8:10-CV-2658 (M. D. Fla., Oct. 20, 2011), where the court dismissed claims against a generic manufacturer that were grounded in negligence, strict liability, breach of warranty, misrepresentation, fraud and negligence *per se.*

Waguespack v. PLIVA, Inc., No. 10-692 (E. D. La., Nov. 3, 2011), where the court rejected the plaintiffs argument based on the defendant's failure to send out "Dear Doctor" letters.

Despite the clear trend that has developed, post-*Mensing*, to dismiss the failure to warn claims against generic manufacturers, there are still a handful of trial judges who are allowing the plaintiff's counsel ample time to develop pleading language that the plaintiffs hope will breathe life into what appear to be claims that are on life support, if not completely dead.

Conclusion

At this point, it is difficult to predict how liability for adverse reactions to generic drugs will be apportioned. It seems unlikely that Congress and the Courts will allow generic manufacturers to remain immune from suit in failure to warn claims forever. The FDA or Congress may impose a duty on generic manufacturers to seek changes for their labels when they become aware of adverse events that are not discussed in their warnings. In any event, this area of the law has witnessed extraordinary changes in the past few years and there is no indication that the evolution is close to an end.

Steven F. Casey

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Steven F. Casey is a partner in Jones Walker's Commercial Litigation Practice Group, and has tried to verdict over 60 cases in state and federal courts in Alabama. His practice is focused on defending pharmaceutical manufacturers in product liability cases, and Steve serves as national counsel for a major generic pharmaceutical manufacturer in several of its product lines. In April, 2010, Steve tried to defence verdict the only metoclopramide case that has gone to trial in the U.S. against a manufacturer. More recently, he spoke at the Defense Research Institute's Drug & Medical Device Litigation Conference in New Orleans on the subject of defending warnings in generic drug litigation.

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