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Practice Tip

Buyer (of the Assets of a Company) Beware

By Kenneth R. Meyer and Brian P. Sharkey

Company X is evaluating whether it should purchase the assets of Company Y, which manufactures lawnmowers. Company X has been looking to break into the lawnmower market and sees the purchase of Company Y's assets as an excellent opportunity to do so. Company X is considering two courses of action if it purchases Company Y's assets: 1) continue the manufacture of Company Y's lawnmower product line, using Company Y's designs, specifications, diagrams, blueprints, personnel, and manufacturing facilities; or 2) cease the manufacturing of the product line, but continue Company Y's ancillary business of repairing and servicing the lawnmowers it sold to its customers. Company X comes to you with a seemingly straightforward question: Under these two scenarios, will it be held liable for product liability claims arising from Company Y's manufacture and sale of defective lawnmowers, even if, as part of the asset purchase, it expressly declines to assume Company Y's liabilities? Unfortunately, based on the current state of the law, you will not be able to provide Company X with an easy, clear-cut answer.

The general rule of corporate-successor liability in the United States is that when a company

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Removal to Federal Court: Death of the First-Served Defendant Doctrine

By John D. Sear

Under 28 U.S.C. §1446(b), defendants seeking to remove a case to federal court must file their notice of removal "within thirty days of receipt, through service or otherwise, of the complaint." Federal circuits historically have split over when the removal period begins and expires. *See generally* Brian Sheppard, Annotation, *When Does Period for Filing Petition for Removal of Civil Action From State Court to Federal District Court Begin to Run Under 28 U.S.C.A. §1446(b)*, 139 A.L.R. Fed. 331, at §§28-29 (1997). Some circuits have held that the removal period begins when the first defendant is served and expires 30 days later, regardless of when other defendants are served. Those circuits subscribing to the "first-served defendant" doctrine hold that defendants served more than 30 days after the first defendant is served are precluded from removing the case if the earlier-served defendant failed to remove within 30 days after service. *E.g., Getty Oil v. Insurance Co. of North America,* 841 F.2d 1254, 1262-63 (5th Cir. 1988) (holding that the 30-day period for removal commences when the first defendant is served). Rejecting the first-served defendant doctrine, other circuits have held that the removal period begins anew each time a new defendant is served. *E.g., Brierly v. Alusuisse Flexible Packaging, Inc.,* 184 F.3d 527, 533 (6th Cir. 1999) (holding that later-served defendants have 30 days to remove even if first-served defendant's 30-day period has already expired). Those circuits reason that it is fundamentally unfair to foreclose removal by later-served defendants, particularly those defendants served after the expiration of the first 30-day period.

One of the U.S. Supreme Court's most recent pronouncements on removal likely sounds the death knell of the first-served defendant rule. Courts that once adhered to the first-served defendant rule have begun to abandon that doctrine in favor of a rule that permits later-served defendants to remove to federal court, even when they are served more than 30 days after service of the first defendant. Thanks to the Supreme Court, lower courts now realize that they may not jeopardize a defendant's rights — implicitly or explicitly — before that defendant is properly served with process and

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Buyer Beware

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sells its assets — as distinguished from stock — to another company, the acquiring company is not liable for the debts and liabilities of the selling company simply because it succeeds to the ownership of the assets of the seller. There are four traditional exceptions to that general rule: 1) the successor expressly or impliedly assumes the predecessor's liabilities; 2) there is an actual or *de facto* consolidation or merger of the seller and the purchaser; 3) the purchasing company is a mere continuation of the seller; or 4) the transaction is entered into fraudulently to escape liability.

Several jurisdictions, however, have developed two other exceptions to the general rule of non-liability. Unlike the traditional exceptions, these newer exceptions do not emphasize the corporate form but instead focus on the operations of the acquiring entity following the asset purchase. One of these exceptions is referred to as the continuity of enterprise exception. The seminal case adopting this exception is *Turner v. Bituminous Casualty Co.*, 244 N.W.2d 873 (Mich. 1976). Under this exception, a successor corporation may be liable for a predecessor company's injury-causing product where the totality of the circumstances surrounding the acquisition demonstrates a basic continuation of the enterprise from the seller to the buyer. *Turner* held that an individual injured by a predecessor's product could establish a *prima facie* case under this exception against the successor if he or she established the following facts: 1) a continuation of the seller corporation, so that there is a continuity of management, personnel, physical location, assets, and general business operations of the predecessor corporation; 2) the predecessor corporation ceases its ordinary business operations, liquidates, and dissolves as soon as practicable; 3) the successor corporation assumes the liability and obligations of the seller ordinarily necessary for the uninterrupted continuation of normal business operations of the predecessor corporation; and 4) the successor corporation holds itself out as the continuation of the predecessor corporation. *Id.* at 883-84.

The second exception is known as the product line exception. That exception was adopted first in California in *Ray v. Alad Corp.*, 560 P.2d 3 (Cal. 1977). *Ray* held that "a party which acquires a manufacturing business and continues the output of its line of products ... assumes strict tort liability for defects in units of the same product line previously manufactured and distributed by the entity from which the business was acquired." *Id.* at 11.

Several other states, including New Jersey, have adopted this exception as well. The product line exception was described by the New Jersey Supreme Court in the following manner: "where one corporation acquires all or substantially all the manufacturing assets of another corporation, even if exclusively for cash, and undertakes essentially the same manufacturing operation as the selling corporation, the purchasing corporation is strictly liable for injuries caused by defects in units of the same product line, even if previously manufactured and distributed by the selling corporation or its predecessor." *Ramirez v. Amsted Indus., Inc.*, 431 A.3d 811, 825 (N.J. 1981). Explaining why it adopted the product line exception, the New Jersey Supreme Court reasoned that the social policies underlying strict product liability are best served by extending strict liability to a successor corporation that acquires the business assets and continues to manufacture essentially the same line of products as its predecessor, particularly where the successor corporation benefits from trading its product line on the name of the predecessor and takes advantage of the accumulated goodwill, business reputation, and established customers of the predecessor.

Despite the creation and adoption of these two additional exceptions by

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Exploring the Broader Application Of the Delaware Court's '*Daubert*' Decision

By William A. Kohlburn

Part Two of a Two-Part Series

The first part of this article discussed the Delaware court's decision in In re Asbestos Litigation, the role of epidemiology in proving causation, and the interpretation of the Daubert decision by several courts. The conclusion examines the role of courts as gatekeepers.

METHODOLOGY NOT CONCLUSIONS

At least two aspects of the *Daubert* ruling in *Asbestos Litigation* could facilitate the opportunity for other toxic tort plaintiffs to get their causation evidence to a jury.

First, this decision squarely holds not only that epidemiology is not required to prove causation, but also that plaintiffs can overcome adverse epidemiology with other types of reliable scientific evidence. The other significant aspect of the *Asbestos Litigation* decision is more a matter of analytical approach, rather than a specific holding. As with most preliminary matters, the proponent of expert testimony under *Daubert* is not supposed to be required to actually "prove" his/her entire case in order to prevail. The issue is supposed to be admissibility, and the inquiry is supposed to focus on the scientific reliability of the underlying principles and methodologies — not the certainty or correctness of the experts' conclusions.

The Delaware court expressly reaffirms these critical analytical tenets, which were first set forth in *Daubert* itself, explaining that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Asb. Litig., *17 (quoting *Daubert*, 509 U.S. at 596). The court goes on to explain, "[i]n establishing the scientific validity of expert testimony, the proponent's focus should be on the methodology applied by the expert rather than the conclusions he generates." Asb. Litig., *18 ("[p]roponents do not need to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable").

According to the court, "[w]hen assessing whether the proponent has met its burden, the trial court does not choose between competing scientific theories, nor is it empowered to determine which theory is stronger." *Id.* "*Daubert* requires only that the trial court determine whether the proponent of the evidence has demonstrated that scientific conclusions have been generated using sound and reliable approaches." *Id.* The court in *Asbestos Litigation* also makes the important observation that reliability is not a mutually exclusive concept, remarking that "[w]hen a trial court determines that an expert's testimony is reliable, this does not mean that contradictory expert testimony by default is unreliable." Asb. Litig., *18. As the court states, "*Daubert* permits testimony that is the product of competing principles or methods." *Id.* In other words, a court's job as gatekeeper does not include choosing which side's experts' opinions are best or even the most reliable; rather, its role is limited to determining if the challenged opinions are reliable enough to go to the jury. Moreover, deciding that a plaintiffs' causation evidence is admissible neither requires nor implies that it is correct, or that defendants' contrary evidence is wrong. In this regard, *Daubert* decisions are a bit like summary judgment (with a differing standard and burden of proof). The issue is whether or not plaintiffs' evidence suffices to create a controversy for the jury to decide, and not how the court might resolve that controversy.

As with its holding concerning epidemiology, this aspect of the court's decision is also well grounded in prior precedent. In a prior decision, the Superior Court specifically observed, "*Daubert* neither requires nor empowers Trial Courts to determine which of several competing scientific theories has the best performance." *Minner v. Amer. Mortgage & Guaranty Co.*, 791 A.2d 826, 848 (Del. Super. Ct. 2000).

In another prior example, a federal court stated, "[t]rial courts should not arrogate the jury's role in evaluating the evidence and the credibility of expert witnesses by simply choosing sides in the battle of the experts." *In re Joint Eastern & Southern District Asbestos Litigation, Maiorana v. U. S. Mineral Products Co.*, 52 F.3d 1124, 1135 (2nd Cir. 1995). The Court, in *Daubert*, states that the inquiry should focus "solely on principles and methodology, not on the conclusions that they generate." 509 U.S. at 595, 113 S.Ct. at 2797.

Here, too, the decision also finds support in the federal reference manual, where Justice Stephen Breyer observes, "[a]ny effort to bring better science into the courtroom must respect the jury's constitutionally specified role — even if doing so means that, from a scientific perspective, an incorrect result is sometimes produced." Ref. Manual on Scientific Evid., Introduction, pp. 4-5. In short, courts are to look at how experts arrive at their conclusions, not how persuasive or compelling those conclusions are.

The *Asbestos Litigation* decision is also noteworthy for what it declines to discuss in any particular detail — namely, the extent to which either side's experts' opinions appear to have been crafted solely for litigation purposes. Although such matters were briefed and argued, the court avoids even mentioning who financed particular studies or how frequently a particular expert has testified for a given side.

This may be due, in part, to the specific circumstances of the cases in question. Each of the four experts presented by plaintiffs has 30 years or so of experience with asbestos issues, including non-litigation treatment of patients, research, and/or publication.

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Delaware

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Thus, it is entirely possible that the court felt that considering such matters was simply unnecessary on the record before it.

On the other hand, it is also possible that the court viewed these matters as going more to credibility and weight, than to reliability. One thing is clear: The court was more concerned with whether or not these experts' methods had non-litigation applications, than with whether their conclusions had any use outside the courtroom.

This approach is consistent with the observation that, under *Daubert*, "expert testimony must be based on at least 'some objective, independent validation of the expert's methodology.'" Ref. Manual on Scientific Evid., Guide on Medical Testimony, p. 442. Basically, even if an expert's conclusions have been generated solely for purposes of litigation, such opinions are nevertheless reliable if the methods used are objectively valid and useful in other contexts. In this regard, the Delaware decision meticulously adheres to its articulated analytical framework by maintaining the focus on methodology, not conclusions, in all respects.

As with the epidemiology issue, the real significance of the Delaware decision's focus on methodology lies less in making innovative departures, and more in its synthesis of the reasoning from authorities that adhere to the principles established by *Daubert*. By expressly focusing on methodology and remaining cognizant of the line between gatekeeper and decision-maker, the Delaware court sets out an analytical framework for resolving these issues that is workable, well-balanced and true to *Daubert*. Subtle nuances — such as how the court addresses the "crafted just for litigation" issue — provide important guidance for how to maintain this focus.

Balancing Gate Keeping with A Flexible Standard

The Delaware court begins its legal analysis with a quote from Judge William Quillen's decision in *Minner*: "*Daubert* is a two-sided coin. On the one side, it is expansive, rejecting the exclusivity of the 'general acceptance' requirement; on the other side, it is restrictive, with a focus on the Trial Judge's responsibility as a gatekeeper on reliability." Asb. Litig., *17. From the perspective of plaintiffs in toxic tort cases, the '*Daubert* coin' has been coming up 'gatekeeper' more often than 'flexible standard' over the past dozen years.

Because the asbestos litigation bar is highly networked, almost every important decision is monitored and cited.

To quote again from Justice Breyer, "[*Daubert*] made clear that the law imposes on trial judges the duty, with respect to scientific evidence, to become evidentiary gatekeepers. The judge, without interfering with the jury's role as trier of fact, must determine whether purported scientific evidence is 'reliable' and 'will assist the trier of fact,' … " Ref. Manual, Introduction, pp. 5-6.

The overall impact of the *Asbestos Litigation* decision is a more appropriate balance between these competing principles. The court accomplishes this by refusing to accord preemptive weight to one type of evidence (epidemiology), focusing on methodology, and respecting the jury's role as trier of facts. This is best summarized by Judge Slights in the *Asbestos Litigation* opinion at *22:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low level exposure to toxic chemicals with human disease. This observation is all the more insightful when considered in the context of a case, like this one, where the sufficiency of the epidemiological evidence is hotly contested by competent scientists on both sides. The Court 'cannot dismiss plaintiffs' experts as poseurs or witnesses for hire. They are serious scientists … ' Thus, even if the Court may agree with [defendant] that its analysis of the state of the epidemiological evidence is correct, the Court does not 'have the authority [under *Daubert*] to conclude a case [as a matter of law] simply because [it] is convinced that one side's science is superior to the others.'

The end result is a framework, which affords plaintiffs in toxic tort cases a fair opportunity to present causation issues to juries. Provided plaintiffs' causation experts use reliable methods that apply beyond the courtroom, it will be for the juries — not the judges — to decide whose conclusions carry more weight.

Circumstances Surrounding The Decision

Beyond these substantive aspects, circumstances surrounding the decision in *Asbestos Litigation* suggest that it may have broader significance. Because the asbestos litigation bar is highly networked, almost every important decision is monitored and cited. The Delaware decision references the four or five other decisions on the particular question of causation and friction materials.

Still, the reasoning in the Delaware *Asbestos Litigation* decision clearly applies beyond the context of asbestos cases. This is particularly true of the holding. Epidemiology is not the only game in town, and the analytical focus is on methodology.

Additionally, the *Daubert* issue in this matter was presented, argued, and considered in an exceptionally thorough manner. This included a four-day evidentiary hearing, pre-hearing and post-hearing briefs, and oral argument both at the close of the hearing and, again, after post-hearing briefing. The resulting opinion is also unusually comprehensive and detailed.

Moreover, the Delaware court system's reputation for being fastidious and even-handed will likely enhance the stature of this decision. It is clear that the court was conscious of how important this decision was to both

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Prescription Drug Litigation Pre-emption

A Continuing Status Report From the Defense Perspective

By Eric G. Lasker

Since the Food and Drug Administration ("FDA") set forth its pre-emption analysis in the preamble to its Jan. 24, 2006 drug-labeling rule, there has been a flood of judicial opinions analyzing the scope and applicability of the pre-emption defense in prescription drug litigation. The cases have been sharply divided, and the defense now appears likely to be a key issue that will be addressed in all cases going forward. In this continuing coverage, I summarize the pre-emption opinions that have been handed down since my last article in the November 2006 issue of this newsletter. For an analysis of the legal arguments in support of pre-emption and the FDA preamble, *see* Eric G. Lasker, *Prescription Drug Litigation Pre-emption Following the FDA Preamble*, LJN's Product Liability Law & Strategy, Vol. 25, No. 4 (October 2006).

At the time of my November 2006 article, a clear majority of courts that had considered the FDA preamble had affirmed the pre-emption defense. Since then, however, the sides have balanced out, as a number of courts have departed from the FDA's analysis as follows:

McNellis v. Pfizer, Inc.

In what can best be described as a mixed result for plaintiffs, the district court in *McNellis v. Pfizer, Inc*., No. Civ. 05-1286, 2006 WL 2819046 (D.N.J. Sept. 29, 2006), rejected the defendants' motion to vacate a pre-preamble ruling denying pre-emption summary judgment, but granted defendants' motion to stay proceedings and allow interlocutory appeal. The district court held that the FDA preamble constituted "an advisory opinion representing the formal position of the FDA," which had more weight than an *amicus* brief. 2006 WL 2819046, at *4. Nonetheless, the court held that the preamble was not entitled to deference, based upon the same reasoning it had applied in previously rejecting the FDA's *amicus* position, *i.e*., that the FDA's position had not been consistent and that deference is due to the FDA solely in cases involving express pre-emption. *Id.* at *8-*10. In allowing interlocutory appeal, the court recognized that its holding conflicted with numerous other recent opinions and the FDA's pre-emption analysis. *Id.* at *11-12.

Perry v. Novartis Pharmaceuticals, Corp.

The plaintiffs in *Perry v. Novartis Pharmaceuticals, Corp*., No. CivA 05-5350, 2006 WL 2979388 (E.D. Pa. Oct. 16, 2006) allege that the prescription drug Elidel® caused lymphoblastic lymphoma. In rejecting the defendant's motion to dismiss on pre-emption grounds, the court rejected the FDA preamble, holding that it was an advisory opinion that was "not entitled to any specific consideration." 2006 WL 2979388, at *4**.** While acknowledging that the "FDA advocates for a somewhat broader scope of preemption," *Id.* at * 5, the court held that prescription drug product liability claims should be pre-empted only where the FDA had specifically considered and rejected the alleged additional warnings urged by the plaintiff. *Id.* at *4-*6. The court concluded that no such FDA consideration had been established for purposes of a motion to dismiss in this case. The court noted, however, that where the "FDA has made a conclusive determination, positive or negative, as to the existence of a link between the drug at issue and some adverse health consequence, state law cannot mandate that a manufacturer include additional warnings beyond those that the FDA has determined to be appropriate to the risk." *Id.* at *6. In so holding, the court expressly rejected plaintiffs' argument that FDA labeling requirements only establish minimum standards: "Because the agency is concerned not solely with maximizing safety, but also with balancing a need for safety with a desire to encourage the widespread use of effective treatments, a specific determination by the FDA that a warning is not warranted is dispositive." *Id.* at *5.

Levine v. Wyeth

Levine v. Wyeth involves a claim that the defendant was negligent in failing to provide adequate warnings of the alleged dangers of injecting the drug Phenergan® directly into a patient's vein. A divided Vermont Supreme Court rejected the defendant's pre-emption argument notwithstanding the defendant's claim that the FDA had denied approval of a proposed stronger warning, holding that the FDA had not clearly explained the reasoning behind its decision. 2006 WL 3041078, slip op. at 6. *Levine* was briefed and argued prior to the FDA's preamble, and much of the court's analysis rejecting the defendants' pre-emption argument is based solely on pre-preamble case law. The court was alerted to the preamble by the defendant after oral argument, however, and expressly rejected the FDA's analysis in its opinion, holding that the preamble was contrary to what it viewed as unambiguous language in the FDA's "changes being effected" regulation, 21 C.F.R. §314.70(c). *Id.* at 9. *But see Id.* at 13 (Reiber, C.J., dissenting). The court also incorrectly held that the Congressional statement (that state law should be pre-empted only in cases of "direct and positive conflict") accompanying the enactment of the 1962 FDCA amendments precluded any consideration whether state law presents an obstacle to the purposes and objectives of congress. Oddly, the court cited in support a case that says exactly the opposite. *Id.* at 7 (citing *S. Blasting Servs., Inc. v. Wilkes County, N.C*., 288 F.3d 584, 591 (4th Cir. 2002)); *contrast S. Blasting Servs*., at 591 ("[t]he 'direct and positive conflict' language … simply restates the principle that state law is superseded in cases of an actual conflict with federal law such that 'compliance with both federal and state regulations is a physical impossibility'"); *Id.* at 590 (defining "actual conflict" to encompass the situation where "state law stands as an obstacle" to federal objectives); *see also Levine*, 2006 WL 3041078, slip op. at 15 (Reiber, C.J., dissenting).

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The Michigan Dioxin Study

Help for Defendants in Toxic Tort Litigation

By Anthony G. Hopp

In August 2006, the University of Michigan's School of Public Health released the initial report in its ongoing study of dioxin exposure in central Michigan. *Measuring People's Exposure to Dioxin Contamination Along the Tittabawassee River and Surrounding Areas* (August, 2006) ("Report") (*www.umdioxin.org*). The University study was prompted by concerns among the population of Midland and Saginaw Counties that dioxin-like compounds from Dow Chemical Company facilities in Midland had contaminated parts of the city of Midland and sediments in the Tittabawassee River (Report, p. 5). The study was not designed to evaluate health effects, but rather to determine whether there was a relationship between levels of dioxin in residential soils and household dust and levels of dioxin in people's blood. *Id.* It also evaluated other factors that could influence blood dioxin levels such as age, diet, hobbies, and employment. *Id.*

The authors found that there was very little relationship between dioxin blood levels and household or environmental dioxin levels. That is, high levels of dioxin in soil or house dust did not translate into high blood dioxin levels. Rather, the most important influences on blood dioxin levels were age, diet, and occupation.

The results of the University study will prove extremely useful in toxic tort cases involving allegations of exposure to dioxin and related compounds, such as PCBs. The results should also be useful in any toxic tort litigation in which a plaintiff claims that high levels of alleged contaminants in soil and household dust constitute proof of plaintiff's exposure to those substances.

The results of the University study will prove extremely useful in toxic tort cases involving allegations of exposure to dioxin and related compounds, such as PCBs.

Dioxin Litigation and the Use of Environmental and Blood Data

Dioxin litigation shows no signs of abating. At this time, there are thousands of individual claims and mass tort claims pending across the country asserting various types of injuries as a result of alleged dioxin contamination. Dioxins, however, are ubiquitous in the environment and in the food supply. *Department of Health and Human Services, Centers for Disease Control, Third National Report on Human Exposure to Environmental Chemicals (July, 1995)* ("Third Report"). Virtually every American has some dioxin in his or her blood. Most soil and water samples collected in the United States reveal trace levels of dioxin (Third Report, p. 135). The situation is no different in Canada, nor presumably in any other developed country. *Environmental Defense, Toxic Nation: A Report on Pollution in Canadians (November, 2005)* p. 1.

Increasingly, plaintiffs and their experts have attempted to prove exposure and causation in dioxin litigation through the use of comparisons between environmental samples and blood tests with the implication that blood levels are a direct consequence of environmental levels. Plaintiff's experts sample the house dust or dirt in or near a plaintiff's home and also test the plaintiff or other members of the community for blood dioxin levels. The experts then attempt to correlate high environmental dioxin levels with high blood dioxin levels. The inference is arguably obvious, *i.e.*, a person whose house or backyard contains high levels of dioxin will have a high blood dioxin level and will, therefore, be at a correspondingly increased risk for alleged dioxin-related health effects.

Leaving aside the very active controversy over the extent to which there are dioxin-related health effects (Cole, P., D. Trichopoulos, H. Pastides, T. Starr, and J.S. Mandel. 2003. Dioxin and cancer: a critical review. Regul Toxicol Pharmacol. 38(3):378-388), the University report will help defendants refute such claims. The University report demonstrates, through the use of a robust data set, that house and soil dioxin levels do not correlate well with blood dioxin levels.

The University Study and Its Findings

The Study Design

The University investigators selected a random sample of Michigan residents in Midland, Saginaw, Jackson, and Calhoun counties, and Williams Township in Bay County (Report, p. 5). Midland and Saginaw residents were thought to have been potentially exposed to dioxin emissions from the Dow Chemical plant in Midland. Jackson and Calhoun Counties were thought to represent areas of Michigan with no known source of dioxin contamination (Report, p. 5).

To be eligible to participate in the study, residents had to be at least 18 years old and have lived at their current address for at least five years. *Id.* Participants submitted to interviews to gather demographic and health data as well as information on diet, recreational activities, occupation, and military history. If eligible, participants were also asked to provide an 80-milliliter blood sample and to consent to sampling of household dust and soil around their homes.

The authors collected blood from a total of 946 people (Report, p. 5), tested 766 properties (Report, p. 22), and administered a questionnaire to 1324 people (Report, p. 30). More importantly, the authors obtained house dust data, residential soil data,

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blood level data and diet/history data from 731 people. *Id.* The University study appears to be the largest study ever published in which blood, personal history, and environmental data were collected from the same people.

The Study Results

The University study concluded that the most important factors related to levels of dioxin in people's blood were their age, gender, and body fat. (Report, p. 6) Older people and people with higher body mass indices had higher dioxin levels. (Report, p. 13) Women under 40 had lower levels than men; women over 40 had higher levels than men. *Id.*

The region where people lived, soil contamination, and household dust contamination accounted for about 1% of the variability in levels of a few of the more "toxic" dioxins in people's blood. For other types of dioxin, soil and dust levels accounted for 0.2% of the variability in peoples' blood. (Report, p. 6) In other words, there was very little, if any, correspondence between environmental levels of dioxins in dust and soil, and the amounts of dioxins in people's blood. Consequently, the intuitive notion that blood dioxin levels are influenced by environmental levels is demonstrably false.

Instead, the lifestyle characteristic that mattered most was diet. People who ate fish, whether store-bought, sport-caught, or from a restaurant had higher blood dioxin levels than non-fish eaters. (Report, p. 15) People who ate fish from and conducted recreational activities in rivers in the allegedly contaminated area had even higher levels. *Id.* at 2.

The median dioxin/furan levels in the blood of people living in Midland and Saginaw was 28 parts per trillion (ppt) on a total toxic equivalency (TEQ) basis. The median level for Jackson and Calhoun counties was 25 ppt. People who lived in the floodplain of the Tittabawassee River averaged 32 ppt, and people who lived near the floodplain had a median level of 29 ppt. *Id.* at 8. The authors of the University study concluded that people who lived in Midland and Saginaw had higher levels than the national average, but as will be set forth below, this may not be the case. As also described below, none of these dioxin blood levels are outside the range of normal as considered by EPA.

[T]here was very little, if any, correspondence between environmental levels of dioxins in dust and soil, and the amounts of dioxins in people's blood.

The most important finding to come out of the University study is that household dust contamination and residential soil contamination do not correlate with blood dioxin levels. This conclusion will be difficult to challenge because the University study contains such a large data set.

Other Measures of Dioxin In Human Blood

There are numerous examples of average or background levels of dioxins/furans in various populations throughout the United States. Some of these were collected in the course of investigating alleged exposure, while others have been collected simply for the purpose of obtaining reference values in unexposed populations.

In 2000, Schecter and Paepke reported U.S. and German control values for dioxins and furans in human blood in the range of 22.6 to 27.6 ppt on a total TEQ basis. Schecter, Arnold and Olaf Paepke, *Dioxin Levels in Milk and Blood From Germany and the USA: Are Dioxin Blood Levels Decreasing in Both Countries, Organohalogen Compounds,* Vol. 48, pp. 68-71 (2000). Some of the pooled samples they used for comparison were Viet Nam veterans who were at least potentially exposed to dioxin as a result of Agent Orange. *Id.* The blood dioxin levels measured in the veterans, however, were on an average lower than the levels measured in the unexposed population.

In 2005, the same authors reported that U.S. blood collected in 2003 had a dioxin/furan TEQ range of 17.2 ppt to 27 ppt. Schecter, Arnold, Olaf Paepke, *et al., Polybrominated Diphenyl Ether Flame Retardants in the U.S. Population: Current Levels, Temporal Trends and Comparison with Dioxins, Dibenzofurans, and Polychlorinated Biphenyls, Journal of Occupational and Environmental Medicine,* Volume 47, pp. 199-211 (2005). They compared these levels to the dioxin level in a pooled blood sample that had been frozen in 1973. The 1973 sample had a blood dioxin level of 85 ppt, total TEQ. *Id.*

In the most recent version of EPA's Dioxin Reassessment (EPA/NAS 2003) the average dioxin/furan concentrations in human tissue are 21.6 ppt TEQ. However, as noted in the text, "*In general, these data indicate that the high-end dose of dioxin-like compounds is likely to be 2 to 3 times higher than the mean." Therefore,* in a normal population, individuals can have dioxin/furan tissue levels of up to 64.8 ppt TEQ. Thus, individuals with no known excess exposure to dioxins/furans can have almost 65 ppt TEQ in their blood and still be considered to be in the upper range of normal: In a typical population there will always be some individuals who will accumulate more dioxins/furans than average because of age, dietary habits, or body composition.

The University study, therefore, presents both exposed and control dioxin blood values that are in line with national averages. While dioxin levels vary with age, and the age distribution of the sample population will heavily influence the average blood dioxin level for the group, it is not unusual to see control populations measure anywhere from the low 20s to the high 30s in ppt of dioxin/furan in blood on a total TEQ basis. In addition, as noted above, the upper range of normal dioxin/furan levels can be much higher.

Part Two of this series will discuss using the University study in dioxin litigation.

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Buyer Beware

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some jurisdictions, a majority of courts continues to adhere only to the traditional four exceptions to non-liability for a successor corporation. In that regard, the *Restatement (Third) of Torts: Products Liability* ("*Restatement*") rejected the *Turner* and *Ray* exceptions and continues to follow only the traditional four. In its comments, the *Restatement* acknowledges that "[a] minority of jurisdictions impose liability on a successor corporation based on a broader concept of continuation of the business enterprise, even when there is no continuity of shareholders, officers, or directors. Some courts hold that the continuation of a predecessor's product line by the successor is sufficient to support imposition of successor liability for harm caused by defects in products sold before the assets transfer." The comments further state that "[a] small minority of courts have fashioned successor liability rules more advantageous to products liability claimants than the rules stated in this Section. ... [The] reasoning [used by those courts] has proven unpersuasive to a substantial majority of courts that have considered the issue."

Whether Company X will be held responsible for the liabilities of Company Y will depend in large part on the jurisdiction in which a given lawsuit is filed, in terms of whether that jurisdiction adheres only to the traditional four exceptions or utilizes one of the newer exceptions. To add further uncertainty to the question of whether a successor corporation will be held liable for the defective products of its predecessor, the viability of the *Ray* and *Turner* exceptions is unsettled in some states, while in other states the issue has never been specifically addressed. It is also impossible to predict how courts will view these new exceptions in the future. In December 2005, the South Carolina Supreme Court rejected an opportunity to adopt the newer exceptions and instead reiterated its adherence to the traditional four exceptions to the general rule of non-liability for successor corporations. *Simmons v. Mark Lift Indus., Inc.*, 622 S.E.2d 313 (S.C. 2005). Similarly, the New York Court of Appeals recently rejected the product line exception. *Semenetz v. Sherling & Walden, Inc.*, 2006 N.Y. LEXIS 1485, at *12 (N.Y. June 13, 2006). In doing so, the New York Court of Appeals resolved a conflict that existed within different departments of the New York Appellate Division about whether New York applied the product line exception. *Id.* at *5 (citing *Hart v. Bruno Mach. Corp.*, 679 N.Y.S.2d 740 (N.Y. App. Div. 1998) (endorsing the product line exception) and *City of New York v. Pfizer & Co.*, 688 N.Y.S.2d 23 (N.Y. App. Div. 1999) (rejecting the product line exception)).

[T]he South Carolina Supreme Court rejected an opportunity to adopt the newer exceptions and instead reiterated its adherence to the traditional four exceptions to the general rule of non-liability for successor corporations.

It is also important to point out that not only can there be uncertainty from state to state in terms of what the governing law is, but there can also be discrepancies between decisions within a given state. Obviously, the determination of whether any of the exceptions applies is a very fact-sensitive, case-specific inquiry that depends on the evidence developed in a particular lawsuit. As a result, there can be seemingly inconsistent decisions even within states where courts are applying the same test because of the nature or quantum of evidence in a given case.

There are also ambiguities within states regarding the breadth or interpretation of the exceptions. For example, although New Jersey has adopted the product line exception, courts have reached different conclusions about its scope. In *Pacius v. Thermtroll Corp.*, 611 A.2d 153 (N.J. Super. Ct. Law Div. 1992), a New Jersey trial court ruled that even though the successor corporation did not continue the product line of its predecessor, it could be held liable because it continued to use the predecessor's name and blueprints and exploited its goodwill. However, in a later case, *Saez v. S & S Corrugated Paper Mach. Co.*, 695 A.2d 740 (N.J. Super. Ct. App. Div. 1997), the New Jersey Appellate Division rejected that notion and overruled *Pacius*, as the court found that it was wrong to impose successor liability on an asset purchaser that discontinues the product line.

There is another significant area where product liability could potentially attach to a successor corporation — and which is relevant to the second question that Company X asked concerning its potential liability if it continues the repair and service business of Company Y. Several jurisdictions have held that a successor corporation can be held liable on a post-sale failure to warn theory under certain circumstances. The *Restatement* has adopted this approach and cites to several jurisdictions, including Michigan, New Jersey, and New York, which impose an independent post-sale duty to warn on a successor corporation when it has a substantial continuing relationship with the customers of the predecessor corporation.

Section 13 of the *Restatement* provides that a successor corporation that acquires assets of a predecessor corporation is subject to liability for harm to persons or property caused by the successor's failure to warn of a risk created by a product sold or distributed by the predecessor if: 1) the successor undertakes or agrees to provide services for maintenance or repair of the product or enters into a similar relationship with purchasers of the predecessor's products giving rise to actual or potential economic advantage to the successor; and 2) a reasonable person in the position of the successor would provide a warning. The *Restatement* rule states that a reasonable person would provide a warning if: 1) the successor knows or reasonably should know that the product poses a substantial risk of harm; 2) those to whom a warning might be provided can be identified

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and can reasonably be assumed to be unaware of the risk; 3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and 4) the risk of harm is sufficiently great to justify the burden of providing a warning.

The comments to the *Restatement* note that courts have recognized four elements as being especially significant in determining whether a post-sale duty to warn can be imposed on a successor: 1) succession to a predecessor's service contracts; 2) coverage of the defective product under a service contract made directly with the successor; 3) actual service of the defective product by the successor; and 4) the successor's knowledge of the existence of defects and the identities of the predecessor's customers who own the defective product. Although a service contract is an important consideration, courts have not found it to be a prerequisite for successor liability under a post-sale warning theory. In that regard, the *Restatement* suggests that if a successor sells spare parts to the predecessor's customers for machinery sold by the predecessor when the successor knows or should know the machinery is defective, then the successor could be held liable. In contrast, when a successor has discontinued both the sale of a predecessor's product line and the provision of services to the predecessor's customers, it may not be in a position to discover defects and provide a warning, and, therefore, not be subjected to liability on a post-sale warning theory.

In short, a successor's provision of repair or maintenance services, or sale of spare parts for the predecessor's product, could subject it to liability on a post-sale warning theory — separate and apart from whether it could be held liable pursuant to the four traditional exceptions to the rule of non-liability, or a continuity of enterprises theory, or a product line theory (in states that accept those additional exceptions). If a successor discovers a defect or a danger in the predecessor's product, the successor could very well have a duty to warn all known owners of that product, and its failure to do so could subject it to liability.

Although a service contract is an important consideration, courts have not found it to be a prerequisite for successor liability under a post-sale warning theory.

To return to the original questions that Company X asked you about its potential liability for defective products manufactured by Company Y, the best answer that you can give is "maybe." Assuming that none of the traditional four exceptions applies to the transaction between Company X and Company Y, it would be prudent for you or Company X to determine the geographical location of Company Y's sales. If Company Y's sales are limited to a specific region, you can examine the law of those states and provide Company X with an analysis of the successor liability law for that region. If, however, Company Y is a national company with sales across the country, then you will have to inform Company X that it may be subject to liability pursuant to one of the newer exceptions in specific states.

At that point, Company X may wish to engage in a cost-benefit analysis and focus on the following non-exhaustive list factors in determining whether it makes sense for it to continue the product line of Company Y: 1) how many lawnmowers has Company Y sold; 2) are there any states in which there is a large number of sales (and, if so, what is the successor liability law in those states); 3) the litigation history of Company Y with respect to its lawnmowers; 4) the types of injuries at issue in product liability cases against Company Y; 5) the substantive product liability laws and damages laws of those states that have adopted one of the newer exceptions; and 6) the profits that Company X anticipates if it continues the product line of Company Y. Finally, with respect to whether it should continue the repair and service business of Company Y, you should tell Company X that it may be opening itself to potential liability on post-sale warning claims.

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Delaware

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sides, when it states: "an incorrect decision can either deprive a plaintiff of warranted compensation while discouraging other similarly situated individuals from trying to obtain compensation, or it can improperly impose liability in a manner that will cause the abandonment of an important product or technology." Asb. Litig., *17. Put differently, this decision should resonate louder in more places, at least in part, because Delaware is not perceived as particularly pro-plaintiff or pro-defendant.

Summary and Conclusions

If one does as the court in *In re Asbestos Litigation* suggests, and reads the *Minner* decision, one will learn that before expert witnesses, there were expert juries. That is, when deciding a controversy required specialized knowledge or expertise, courts would empanel jurors from the requisite profession to hear the case. In this respect, the roots — to which the decision refers in *Asbestos Litigation* — run even deeper than *Daubert* itself.

Daubert obliges a court to screen out questionable science. It does not empower it to resolve scientific disputes that are for academics outside the courtroom and juries inside the courtroom. In the end, the enduring influence of the Delaware *Asbestos Litigation* decision will likely stem from precisely that — the fact, that it respects both the jury's role as fact-finder and the ability of jurors to perform that function. Ultimately, this decision is not just a victory for toxic tort plaintiffs, but for the integrity of the jury system itself.

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First-Served

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given an opportunity to be heard. Courts have abandoned the first-served defendant doctrine out of a recognition that it does not comport with basic notions of due process and fundamental fairness. The abandonment of the first-served defendant doctrine is long overdue.

MURPHY BROS.: THE BEGINNING OF THE END

Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc., 526 U.S. 344 (1999), ushered in the beginning of the end of the first-served defendant doctrine. In *Murphy Bros.*, the plaintiff filed a complaint against the defendant in Alabama state court. The plaintiff did not serve the complaint on the defendant, but faxed a "courtesy copy" of the complaint to one of the defendant's vice presidents. After settlement negotiations failed, the plaintiff served the complaint according to Alabama law, prompting the defendant to remove the case to the Northern District of Alabama 30 days later. The plaintiff moved to remand, arguing that the removal was untimely because the defendant filed more than 30 days after the defendant received the faxed copy of the complaint.

The district court rejected the plaintiff's argument, ruling that service of process is required to start the time for removal. The 11th Circuit reversed, holding that the time for removal started when the defendant received the courtesy copy of the complaint.

The Supreme Court granted certiorari to address the issue of whether "the named defendant must be officially summoned to appear in the action before the time to remove begins to run." 526 U.S. at 347. The Supreme Court held that the time for removal does not commence until service of process is completed, regardless of when the defendant *receives* the summons or complaint:

> Service of process, under long-standing tradition in our system of justice, is fundamental to any procedural imposition on a named defendant. At common law, the writ of *capias ad respondendum* directed the sheriff to secure the defendant's appearance by taking him into custody. The requirement that a defendant be brought into litigation by official service is the contemporary counterpart to that writ.
>
> In the absence of service of process (or waiver of service by the defendant), a court ordinarily may not exercise power over a party the complaint names as a defendant. Accordingly, one becomes a party officially, and is required to take action in that capacity, only upon service of a summons or other authority-asserting measure stating the time within which the party served must appear and defend. Unless a named defendant agrees to waive service, the summons continues to function as the *sine qua non* directing an individual or entity to participate in a civil action or forgo procedural or substantive rights.
>
> When Congress enacted §1446(b) [establishing the 30-day removal deadline], the legislators did not endeavor to break away from the traditional understanding. *Id.* at 350-51 (citations omitted).

The Supreme Court found support for its construction of §1446 in the Seventh Circuit case of *Silva v. Madison*, 69 F.3d 1368 (7th Cir. 1995), which aptly observed that "nothing would justify ... concluding that the drafters, in their quest for evenhandedness and promptness in the removal process, intended to abrogate the necessity for something as fundamental as service of process." *Murphy Bros.*, 526 U.S. at 355 (quoting *Silva*, 69 F.3d at 1376). Hence, without service of process on the defendant, the defendant's removal rights cannot be jeopardized through something as seemingly fortuitous as the *timing* of service.

THE TIDE BEGINS TO TURN

The Eighth Circuit was one of the first circuits to face this issue post-*Murphy Bros.*, in *Marano Enterps. of Kansas v. Z-Teca Restaurants, L.P.*, 254 F.3d 753, 757 (8th Cir. 2001). The plaintiff in *Marano* filed suit against five defendants in Missouri state court, alleging fraud, breach of contract, and other claims. The plaintiff served two defendants on Feb. 1, 2000, and two more on Feb. 3, 2000. On March 3, 2000, all defendants, including the one who had not yet been served, jointly filed their notice of removal to the Western District of Missouri. The plaintiff moved for remand, arguing that the removal was untimely under the first-served defendant doctrine, but the district court denied the motion. On the plaintiff's appeal, the Eighth Circuit applied *Murphy Bros.* and affirmed the district court's ruling:

> Having examined the cases in this area of the law, we must say that we find neither position particularly compelling, as both are susceptible to abuse and have potential to create inequities. We are convinced, however, that the legal landscape in this area has been clarified, and perhaps the definitive answer portended, by the Supreme Court's decision in [*Murphy Bros.*]
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> * * *
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> We hold that the later-served defendants in this case had thirty days from the date of service on them to file a notice of removal with the unanimous consent of their co-defendants, even though the first-served defendants did not file a notice of removal within thirty days of service on them. *Id.* at 756, 757.

Applying *Murphy Bros.* and *Marano*, the Seventh Circuit rejected the first-served defendant doctrine in *Boyd v. Phoenix Funding Corp.*, 366

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First-Served

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F.3d 524 (7th Cir. 2004). The court in *Boyd* recognized that the question of "whether a later-named defendant can remove an action pending in state court outside of the original thirty-day window is a question of first impression" in the Seventh Circuit. *Id.* at 530. Understandably, the court looked to *Murphy Bros.* for guidance. The court acknowledged that a court may exert power over a named defendant only after that defendant has been served with process and summoned to appear and defend. It emphasized, however, that "the removal statutes do not permit defendants deliberately to manipulate" their positions "so that the 30-day time limit on removal found in §1446(b) can be avoided." *Id.* at 530-31. Although the court remanded the case for further fact-finding by the district court, it made clear that the "first-served defendant" doctrine is a thing of the past absent evidence of conduct equating collusion among defendants.

The two leading federal practice treatises once "diverge[d] in their recommendations of how to resolve this issue." *Id.* at 530 (explaining that Wright & Miller recommends the "later-served defendant" rule while Moore's Federal Practice recommends the "first-served defendant" rule). That divergence has since disappeared. *Compare* 14C Charles A. Wright *et al.*, FEDERAL PRACTICE AND PROCEDURE: JURISDICTION AND RELATED MATTERS §3732, at 116 (Supp. 2005) (recognizing rejection of first-served defendant doctrine by courts following *Murphy Bros.*) *with* 16 James W. Moore *et al.*, MOORE'S FEDERAL PRACTICE §107.30[3][a][i], at 107-163 (3d ed. 2005) ("[I]t is likely that the Court may decide that the later served defendants may not have their removal right compromised before they are served, and that they ought to have the opportunity to persuade the earlier served defendants to join the notice of removal. Thus, the fairness approach may well, and should, supercede [*sic*] the unanimity rule.").

OLD HABITS DIE HARD

One court has characterized the first-served defendant doctrine as "counter-intuitive" in light of *Murphy Bros. See Orlick v. J.D. Carton & Son, Inc.*, 144 F. Supp. 2d 337, 343 (D.N.J. 2001). While it appears that a growing number of courts agree, some courts continue to hold fast to the doctrine.

The Supreme Court correctly acknowledged in* Murphy Bros. *that '[s]ervice of process, under longstanding tradition in our system of justice, is fundamental to any procedural imposition on a named defendant.'

In *Cellport Systems, Inc. v. Peiker Acustic GMBH & Co. KG*, for example, the District of Colorado found "nothing in the *Murphy* decision ... that undermines the first-served defendant rule or its rationale." 335 F. Supp. 2d 1131, 1134 (D. Colo. 2004). In *Cellport Systems*, the plaintiff sued two defendants, serving one on Feb. 18, 2004, and one on June 9, 2004. The first-served defendant did not remove, but the later-served defendant did, within 30 days after service of the complaint. The district court granted the plaintiff's motion to remand on the ground that the unanimity requirement could not be met after the first-served defendant failed to remove during its 30-day period following service:

> When the first served defendant allows the thirty-day period to lapse, he has effectively waived his consent to removal. Therefore, any effort to remove by a subsequently served defendant after that period would be futile, because the first-served defendant would be unable to join that petition and the case therefore would be unremovable. *Id.* at 1133 (quotations omitted).

The court in *Cellport Systems* attempted to distinguish *Murphy Bros.*, rather unsatisfactorily, on the ground that it involved a single defendant and, therefore, "did not consider the issues presented by the separate question of the statutory period for removal in cases involving multiple defendants." *Id.* at 1134. The District of Colorado is by no means alone in adhering to the first-served defendant doctrine in spite of *Murphy Bros. See, e.g., Baych v. Douglass*, 227 F. Supp. 2d 620, 622 (E.D. Tex. 2002) (declining to "extend [*Murphy Bros.*'] reasoning to overrule the well-established Fifth Circuit precedent of *Getty Oil*"); *Biggs Corp. v. Wilen*, 97 F. Supp. 2d 1040, 1045 (D. Nev. 2000) (citing *Murphy Bros.* for proposition that formal service of process is required to trigger the 30-day removal period but nonetheless adhering to the first-served defendant doctrine as "the better rule").

CONCLUSION

The Supreme Court correctly acknowledged in *Murphy Bros.* that "[s]ervice of process, under longstanding tradition in our system of justice, is fundamental to any procedural imposition on a named defendant." The first-served defendant doctrine cannot be reconciled with "that longstanding tradition in our system of justice," and has been soundly — and wisely — discredited and rejected by the growing number of courts facing the issue in multiple-defendant cases.

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CASE NOTES

REMOVAL TO FEDERAL COURT DENIED WHERE THERE WAS NO EVIDENCE OF FRAUDULENT JOINDER

Where one defendant cannot demonstrate that another defendant was fraudulently joined to prevent removal to federal court, and where an issue of law has not been determined by the state court where the litigation would occur, the federal court will not assume jurisdiction. *Moore v. Medtronic, Inc., et al.*, Case No. 2:05-CV-01329-KJD-PAL, June 26, 2006.

Moore suffered from monoplegia after a catheter placed into her during surgery slipped into her spinal cord. She commenced an action for negligence, breach of warranties, strict liability, and joint and several liability in Nevada state court against the manufacturer of the catheter, as well as hospital personnel, and a sales representative of the manufacturer of the catheter. The defendant-manufacturer filed a notice of removal based upon diversity jurisdiction, and the plaintiff moved to remand because the sales representative defendant was a Nevada resident. The defendant-manufacturer argued that the plaintiff fraudulently joined the sales representative to prevent diversity jurisdiction.

The federal court granted the plaintiff's motion and held that there was no evidence of fraudulent joinder. It further noted that Nevada case law had not yet addressed whether a sales representative for a manufacturer could be considered a "seller" for the purpose of liability under a strict product liability theory. It noted that other jurisdictions were split on the issue, and it would not decide the issue for the state.

LACK OF CAUSATION EVIDENCE LEADS TO REJECTION OF MESOTHELIOMA CLAIM

Without proof of causation, an employer cannot be held liable for an employee's illness. *Jones v. ExxonMobil Oil*, S145590, Cal.Super.Ct., First Appellate District, Division Three, No. A114614, Aug. 31, 2006.

A San Francisco County jury rejected the claims of a former oil refinery employee who alleged his job had caused mesothelioma. Richard Jones, 67, a retired pipe fitter, worked for several contractors at the ExxonMobil Oil Refinery in Torrance for less than five months in 1966. Jones alleged that ExxonMobil Oil Corp. negligently allowed him to be exposed to asbestos dust, contributing to his contraction of mesothelioma. ExxonMobil argued that it neither retained nor exercised control over the area in which Jones worked, and that its programs for dust control were among the best being used in the mid-1960s. Defense counsel also noted that in the years following his work with ExxonMobil, Jones worked extensively with crocidolite, one of the most potent forms of asbestos.

The California Supreme Court ordered the petition for review withdrawn pursuant to petitioner's request.

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Pre-emption

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Desiano v. Warner-Lambert & Co.

Desiano v. Warner-Lambert & Co., Nos. 05-1705, 05-1743, and 05-1745, 2006 WL 2846454 (Oct. 5, 2006) does not involve implied conflict pre-emption of prescription drug claims *per se*, but, rather, addresses the question of whether the "fraud on the FDA" exception to a Michigan statute barring product liability claims against FDA-approved prescription drugs is pre-empted by the U.S. Supreme Court's ruling in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The Second Circuit held that the exception was not pre-empted, thereby creating a Circuit split with the U.S. Court of Appeals for the Sixth Circuit, which had previously held the exception to be pre-empted except where the FDA had made the fraud determination. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). Although neither briefed nor argued in the case — and by the court's own admission largely irrelevant to the analysis of the Michigan statute — the court reached out *sua sponte* to express its view that the FDA preamble is not entitled to deference absent a clear expression of Congressional intent in favor of pre-emption. *Desiano*, 2006 WL 2846454, at *11 n.9. The defendant has filed a motion for rehearing and rehearing *en banc*.

CONCLUSION

With pre-emption motions pending in numerous prescription drug cases across the country, and pre-emption cases on appeal in a number of federal appellate courts, including the Third and Seventh Circuits, the scope and shape of pharmaceutical conflict pre-emption remains an open question. The numerous opinions issued over the past year in the wake of the FDA preamble make clear, however, that the pre-emption defense has taken a new and prominent role in prescription drug litigation.

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