2013

PRODUCT LIABILITY

ANNUAL REVIEW

THE MOST SUCCESSFUL INDUSTRY PLAYERS MAXIMIZE REWARD AND MINIMIZE RISK—AND WE HELP THEM DO IT.

INSIDE

LETTER FROM CHAIR

I am pleased to present you with the 2012 Product Liability Annual Review, marking another successful year for Morrison & Foerster's Product Liability Group. In 2012, my colleagues and I continued to build on our position as a world-class product liability group.

We continue to handle high-stakes, high-profile matters for clients in the pharmaceutical, aviation, and consumer-products industries. In 2012, we litigated more than 400 active product liability matters, and were retained in more than 100 new engagements. We continued our successful trial track record with jury trial victories, and successfully resolved numerous other cases through motion practice and favorable settlements. We also advised our clients on a wide range of risk mitigation issues, including product labeling, risk assessment, and responses to safety incidents.

Our commitment to training, mentoring, and thought leadership ensures that our attorneys will stay at the top of this field. We instituted a seven-part training series on pharmaceutical and medical-device product liability litigation, a two-part series on insurance law, and a four-part series on consumer product issues. Our talented writers also published more than 30 legal updates and articles throughout 2012.

Our hard work and client dedication were recognized throughout the industry, as evidenced by our high-level rankings in publications such as *Chambers USA*, *Legal 500 US*, and *Benchmark Litigation*.

We would like to thank you, our clients, for the privilege of representing you in some of your most important and complex legal matters. We look forward to representing your interests around the globe in 2013, and wish you all the best.

Sincerely,

Erin Bosman
Chair, Product Liability Group

AVIATION
KEY MATTERS

Recognized as being among the top aviation litigation practices in the United States, we have more than three decades of complex aviation case experience. Many of our attorneys have military or civil aviation backgrounds, and know and understand the technical aspects of aviation litigation. This firsthand experience helps us devise creative and innovative approaches to extraordinarily complex matters, and deliver winning results.

SILVEY V. CESSNA AIRCRAFT COMPANY

Secured a **"take nothing" verdict** in favor of Cessna Aircraft Company in a four-week trial in the U.S. District Court for the Northern District of Texas. The jury concluded that the crash of a Cessna Caravan 208B aircraft piloted by plaintiffs' decedent on November 8, 2002, near Parks, Arizona, was primarily caused by pilot error.

TAYLOR V. HONEYWELL INTERNATIONAL INC.

Won summary judgment on behalf of Honeywell International against a pilot claiming posttraumatic stress disorder after his Boeing 747, United Airlines Flight 901, "almost crashed" following an approach into San Francisco International Airport due to an alleged defect in Honeywell's flight management system.

MORRIS V. CESSNA AIRCRAFT COMPANY

Represented Cessna Aircraft Company in litigation arising from the crash of a Cessna Caravan 208B near Ducote Airpark, Texas, on January 24, 2003, in which the two pilots were injured. After we won 20 of our 22 motions in limine during pretrial proceedings, we were able to negotiate a **favorable settlement** for Cessna.

LEE V. THE BOEING COMPANY, ET AL.

Secured the dismissal of Honeywell International from a personal injury suit filed in the U.S. District Court for the Middle District of Alabama by a passenger on a U.S. Army CH-47F that crashed on July 26, 2010, while conducting a "Green Ring" supply and personnel movement mission near Kabul, Afghanistan.

YOUNAN V. MD HELICOPTERS, INC.

Represent MD Helicopters, Inc., in a lawsuit arising from the **crash of an MD600N helicopter operated by the U.S. Border Patrol** in California. Plaintiffs are the injured pilot and copilot, as well as their wives. The plaintiffs allege that the helicopter experienced an engine failure and subsequent hard landing during an attempted autorotation. The plaintiffs also allege that MDHI provided improper autorotation training.

GETZ V. HONEYWELL INTERNATIONAL INC.

Defeated plaintiffs' application to the Ninth Circuit for rehearing and rehearing en banc of its holding that Honeywell International Inc. and other government contractor defendants were not liable for the crash of an Army special operations Chinook in Afghanistan on February 17, 2007. The plaintiffs' application for writ of certiorari was also denied by the U.S. Supreme Court.

AVIATION TRENDS

The year 2012 was one of little turbulence in the field of aviation product-liability litigation. There were fewer major accidents, and thus fewer lawsuits filed. The aviation insurance market followed suit, with another year of low losses preserving soft-market conditions. Similarly, the legal landscape was marked not by major changes in the law, but by cases that refined the contours of existing doctrines. Below are some of the highlights from 2012 in the areas of standard-of-care preemption, *forum non conveniens*, and the duty to train—as well as a look ahead to 2013.

Standard-of-Care Preemption

In 2012, courts continued to define the scope of standard-of-care preemption in the field of aviation safety. Decisions from California and New York illustrate how courts may be expected to apply the growing body of case law declaring that the Federal Aviation Act of 1958 (FAAct) and the Federal Aviation Regulations (FARs) "thoroughly occupy" the field of aviation safety, and preempt state standards of care.

In March 2012, the California Court of Appeal, Second District, addressed whether nonmandatory safety standards issued in FAA Advisory Circulars preempt state tort law regarding the standard of care. *Sierra Pacific Holdings, Inc. v. County of Ventura*, No. B232307, slip op. (Cal. App. Mar. 20, 2012). The court held that they do not. The court found that FAA Advisory Circulars are just that—advisory—and such nonmandatory federal standards are not federal "law" leading to Supremacy Clause preemption.

The case arose from an aircraft owner's lawsuit against an airport for negligently creating a dangerous condition at the airport that resulted in damage to the aircraft. While the trial court found that FAA Advisory Circulars governed the standard of care, the California Court of Appeal reversed. The appellate court acknowledged that the Second, Third, Sixth, and Tenth federal circuit courts of appeals had held that FAA regulations impliedly preempt state tort law regarding the standard of care in the field of aviation safety. Accordingly, the California court admitted that, because the Advisory Circular at issue implicated the field of aviation safety, the Advisory Circular arguably would preempt state law under the approach of these federal courts.

But the court then turned to the Ninth Circuit approach to implied preemption, and analyzed whether the FAA had issued "pervasive regulations" in the specific area covered by the tort claim. Because Advisory Circulars by definition are guidelines, not rules, the court found that they cannot constitute pervasive federal "law" sufficient for standard-of-care preemption.

A New York state trial court reached a different result in September 2012. In *In re: Air Crash near Clarence Center, New York*, 951 N.Y.S.2d 841, 2012 WL 4324940 (N.Y. Sup. Ct. Sept. 21, 2012), the Erie County court held that federal standards of care did apply to the plaintiffs' claims of negligent pilot hiring, training, and retention. This case arose out of the February 12, 2009 crash of Continental Connection Flight 3407. The plaintiffs alleged that, in addition to the pilot's negligence in operating the airplane, defendants Colgan Air Inc. and Pinnacle Airlines Corp. negligently hired, trained, and retained the pilot, who allegedly had a history of failed flight tests and unsafe flying tendencies. Colgan and Pinnacle moved for an order stating that federal standards of care governed the plaintiffs' claims.

The New York court agreed. The court concurred with the "litany of federal cases" holding that the FAAct and the FARs "'thoroughly occupy' the field of aviation safety by establishing 'complete and thorough safety standards for interstate and international air transportation that are not subject to supplementation by, or variation among, jurisdictions.'" The court then concluded that preemption applied because the plaintiffs' allegations "fall squarely within the broad field of air safety." Furthermore, the court found that the regulations relating to pilot training, certification, and hiring were exhaustive.

Finally, the court had little sympathy for the argument that applying federal standards of care would effectively bar the plaintiffs' claims. As the court stated: "Admittedly, the application of the doctrine of implied preemption to thwart state standards of care may sometimes affect the ultimate outcome of a case, possibly resulting in dismissal of a claim." The preemption doctrine nonetheless prevailed.

Forum Non Conveniens

An Illinois Supreme Court ruling in December 2012 represented an encouraging turn for aviation defendants in a state where it has been nearly impossible to achieve dismissal on *forum non conveniens* grounds in foreign aviation accident cases.

The asbestos case *Fennell v. Illinois Cent. R.R. Co.*, 2012 IL 113812 (Dec. 28, 2012), involved a defendant's *forum non conveniens* motion where the plaintiff resided in Mississippi, the injury occurred in Mississippi or Louisiana, and the defendant maintained offices in Mississippi and Tennessee. The only connections to Illinois were the locations of the attorneys' offices, some documentary evidence, and the location of one of the plaintiff's experts. Reversing the trial and appellate court decisions denying dismissal on *forum non conveniens* grounds, the Illinois Supreme Court held that courts must look at all public and private factors in the *forum non conveniens* analysis, and not focus on only one or two factors.

Although it arose in the asbestos context, *Fennell*'s emphasis on considering all public and private factors in the *forum non conveniens* analysis is a promising shift for aviation defendants trying to avoid a historically plaintiff-friendly forum. The Illinois Supreme Court seems to be always open to aviation accident cases, no matter how little connection to Illinois the cases bear. Past attempts by aviation product-liability defendants to achieve *forum non conveniens* dismissal have had little success. *Fennell* therefore may prove to be a useful weapon for aviation defendants in Illinois state court looking for a more convenient forum in the United States or abroad. The opinion cuts against the Illinois appellate court's theory in 2009's *Vivas v. Boeing* that where there is evidence scattered across multiple states and countries, no one forum can be more convenient. Further, if unsuccessful at the trial court level, *Fennell* will give ample ammunition to attack any *forum non conveniens* denial on appeal where the trial court did not consider all private and public interest factors in the analysis.

In a recent unpublished opinion in the aviation context, the Ninth Circuit also affirmed the *forum non conveniens* dismissal of a number of lawsuits arising from the 2008 crash of a Spanair flight in Madrid. *Fortaner, et al. v. The Boeing Company, et al.*, 2013 U.S. App. LEXIS 2013. The Ninth Circuit ruled that Spain offered both an available and adequate alternative forum for the lawsuits, and that the public and private interest factors weighed in favor of dismissal to Spain. Although the opinion was unpublished, defendants in the Ninth Circuit may cite it as persuasive authority in cases involving foreign aviation accidents.

Duty to Train

In a July 2012 ruling, the Minnesota Supreme Court addressed whether a manufacturer or supplier's duty to warn includes a duty to train. *Glorvigen v. Cirrus Design Corp.*, No. A10-1242, et al., 816 N.W. 2d 572, 2012 WL 2913203 (Minn. July 18, 2012). The court held that, under Minnesota negligence law, manufacturers and suppliers do have a duty to warn users of foreseeable dangers inherent in a product, and that this duty includes a duty to give adequate instructions on the safe use of the product. The court specifically declined, however, to extend this duty to requiring suppliers or manufacturers to *train* users in the safe use of their products.

Glorvigen arose out of the crash of a Cirrus SR22 airplane in January 2003, which killed both men on board and destroyed the hull. Combined lawsuits brought by the estates of the decedents against Cirrus, as the manufacturer and seller, alleged breach of the duty to warn and to provide adequate instructions for the safe use of its airplanes. As part of the pilot/owner's purchase of the airplane, Cirrus provided him with a two-day training program—including both ground school and flight instruction—designed to help already-licensed pilots transition to the SR22. The pilot successfully completed the transitional training, but apparently did not receive a part of the in-flight instruction that practiced a maneuver for recovery from unexpected flight while under Visual Flight Rules (VFR) into Instrument Meteorological Conditions (IMC). The crash resulted from such an encounter and the improper recovery from VFR into IMC.

The Minnesota Supreme Court held that failing to provide the applicable in-flight training did not amount to a breach of the duty to warn. While there was no dispute that, as the supplier and manufacturer of the airplane, Cirrus had a duty to warn foreseeable users like the pilot/owner, and that the duty to warn includes a duty to give adequate instructions on the safe use of Cirrus airplanes, the court held that the duty to warn was satisfied through written instructions. The court noted that "[t]he duty to warn has never before required a supplier or manufacturer to provide training, only accurate and thorough instructions," and an imposition of a duty to train would require an "unprecedented expansion of the law."

The court also rejected the idea that Cirrus's failure to provide the applicable flight instruction, as Cirrus had contracted to do, could support a negligence cause of action. The court reasoned that fundamental differences between contract and tort law mean that a breach of a duty imposed by contract does not result in responsibility for tort damages. The *Glorvigen* ruling thus maintains the crucial difference between responsibilities voluntarily assumed in contract and those imposed by law in tort.

While *Glorvigen* applied only Minnesota law and did not reach the issue of educational malpractice that was fully analyzed by the lower court's opinion, it is persuasive authority that may be applied to claims brought under similar negligence laws in other states. The case therefore provides another useful tool in the defense of claims arising out of allegedly inadequate pilot training.

Looking Ahead to 2013

As the decline in accidents over the past several years makes clear, flying has never been safer. All signs indicate that this trend will continue in the coming year. Thus, barring any major accidents, the forecast for 2013 promises another year much like the last one in the field of aviation litigation.

CONSUMER PRODUCTS AND TOXIC TORTS
KEY MATTERS

We defend and provide counsel to product manufacturers and suppliers of all types of products. We serve as trial and national coordinating counsel in product-liability and toxic tort cases, including class actions, multiparty serial tort litigation, mass tort litigation, and multidistrict litigation proceedings. We bring to every case a wealth of experience, a keen understanding of the multifaceted issues confronted by manufacturers, and the skills and knowledge to communicate scientific and medical defenses to juries.

IN RE HYDROXYCUT MARKETING AND SALES PRACTICES LITIGATION

Serve as lead national trial and coordinating counsel in multidistrict and state court litigation, in which plaintiffs allege that a line of nutritional supplement products caused a variety of medical ailments, including liver damage. Cases were filed on behalf of more than 700 plaintiffs in federal court and in Pennsylvania, New Jersey, and California state courts. We obtained preliminary **approval of the class action settlement** in January 2013, and are working to resolve the personal injury claims through a master settlement with the plaintiff steering committee.

THE NEWARK GROUP, INC. V. DOPACO, INC.

Successfully **resolved one of the year's largest cases brought in California under the Resource Conservation and Recovery Act** by securing a federal court injunction for the environmental cleanup of a Stockton, California industrial site owned by The Newark Group.

ORANGE COUNTY WATER DISTRICT V. SABIC, ET AL.

Represent two companies in **one of the largest groundwater contamination cases of its kind**. This case is expected to result in important precedent regarding a water district's ability to create its own "mini-Superfund."

MCADAMS V. MONIER INC.

Won a complete defense victory after an eight-week jury trial in a case seeking more than $250 million in compensatory damages, plus punitive damages on behalf of 128,000 potential class members. The plaintiff claimed that our client Monier falsely advertised its "50-year" and "lifetime" tiles without disclosing that weathering could erode the tiles before their expected useful lives. The jury initially awarded a $7.4 million verdict, but three weeks later the judge set aside the verdict, finding that the statistical sampling method used by the plaintiffs' expert to determine class size, liability, and damages could not be supported.

CYTEC INDUSTRIES

Coordinating the defense of more than **70 asbestos-containing-product lawsuits** pending in California, Delaware, Illinois, Michigan, Minnesota, Mississippi, Missouri, New York, Maryland, Texas, and Wisconsin, as well as in multidistrict proceedings pending in Philadelphia. The plaintiffs allege personal injury and wrongful death due to exposure to asbestos fibers in the workplace.

COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS COFFEE LITIGATION

Represent virtually **every major producer of packaged or brewed coffee sold in California**, including Starbucks, Folgers, Green Mountain Roasters, illy, and Maxwell House, in two lawsuits brought by the Council for Education and Research on Toxics regarding the presence of acrylamide in coffee.

PRODUCT LIABILITY ADVISEMENT

Advised an **upscale home furnishings retailer** regarding the use of a warranty on outdoor furnishings, and regarding warranty disclaimers and sales contract provisions with respect to the resale and associated labeling of fixtures used in the store.

RETURNED GOODS HAZARDOUS WASTE LITIGATION

Defended a national retailer against prosecutors alleging that damaged or returned goods must be managed as hazardous waste. While similar cases filed against other major retailers have settled for $8 million – $25 million, we **settled our client's case** for under $4 million by aggressively educating the prosecutors on our client's existing procedures for waste management, and promptly making revisions suggested by the state.

LEAD AND ARSENIC IN FRUIT AND JUICE LITIGATION

Represent 21 food and beverage companies in the defense of a California Proposition 65 lawsuit, as well as federal and state class actions alleging that their 100% fruit juice, packaged fruit, and baby food products expose consumers to lead and arsenic at levels requiring warning or disclosure. We quickly shut down an initial wave of publicity related to these claims; avoided the possibility of the California attorney general taking over the prosecution of the Proposition 65 claims; and moved the class claims into an MDL proceeding in federal court. Our motion to dismiss the class claims based on the plaintiff's lack of cognizable injury and Article III standing was granted by the MDL judge; subsequent class claims filed in Arkansas, Texas, and California have been dismissed on the same basis.

CONSUMER COMPLAINT ADVISEMENT

Advised a **major film company** on several consumer product issues, including its response to customer complaints regarding potential product issues, and its negotiation of product liability protections in a distributor contract with a Danish toy distributor.

CONSUMER PRODUCTS AND TOXIC TORTS TRENDS

In 2012, the U.S. Consumer Product Safety Commission (CPSC) continued to take a more aggressive regulatory approach toward consumer products. Product manufacturers and even some courts resisted. The coming year may see even more pressure on product manufacturers, with the CPSC enforcing additional regulatory requirements for children's products, and threatening higher civil penalties for any violation of the Consumer Product Safety Improvement Act (CPSIA). Compounding those developments is a trend among some courts to allow plaintiffs to file suit even if they did not purchase the particular consumer product.

CPSC's Increasing Administrative Complaints – Are Warnings No Longer Enough?

The CPSC accelerated its use of administrative complaints in recalling consumer products in 2012, rather than working with manufacturers to adopt packaging and warning alternatives. For example, the CPSC obtained the agreement of about a dozen manufacturers to voluntarily stop manufacturing, importing, distributing, and selling small rare-earth magnet adult desk toys, due to the concern that children or teenagers might swallow the magnets and suffer serious injuries. When manufacturers and importers refused to conduct a similar voluntary recall of Buckyballs and Zen Magnets, the CPSC brought administrative complaints to stop their production and sale. Only Zen Magnets is fighting the CPSC lawsuit now. Buckyballs has stopped production and gone out of business, and its website posted a notice blaming their business failure on the CPSC's "baseless and relentless legal badgering."

The magnet recalls appear to reflect the CPSC's view that, at least for some categories of products, no warning will be sufficient to alleviate the perils presented. This seems especially true for products that are intended for adult use but are also appealing to children. Indeed, in November 2012, the CPSC went so far as to issue a safety alert to parents to keep children away from single-use laundry pods, because their bright colors might attract children. The CPSC again questioned the efficacy of warnings in its December 2012 administrative complaint against the maker of Nap Nanny infant recliners. The CPSC had worked with Nap Nanny in 2010 to voluntarily recall one infant recliner model and improve instructions and warnings to consumers who owned a different model. Despite these improved warnings—that the CPSC had a hand in drafting—the 2012 complaint sought the recall of all Nap Nanny model recliners, in part due to the allegation that the warnings were not effective. Nap Nanny is now out of business, just like the maker of Buckyballs.

CPSC's New Interpretation of Section 6(b) Requirements to Announce Investigations

The CPSC also took an aggressive stance in September 2012, when it announced a new interpretation of Section 6(b) of the Consumer Product Safety Act during a CPSC Safety Academy workshop. The interpretation would permit the CPSC to announce that it is investigating a product or a company based only on the information contained in an initial or full Section 15 report, even though many such self-reports result in no corrective action. (A Section 15 report is filed by a consumer products manufacturer, importer, distributor, or retailer to notify the CPSC of a failure to comply with an applicable consumer product safety rule or standard, or of a product defect that could create a substantial product hazard or an unreasonable risk of serious injury or death.)

The National Association of Manufacturers (NAM) submitted a letter, signed by 39 trade associations, opposing the CPSC's suggested interpretation as a departure from the CPSC's 30-year policy of not disclosing information relating to pending agency investigations until some resolution is reached. The NAM letter argues that the interpretation violates the plain reading of Section 6(b), which provides for public disclosure only under certain circumstances. The NAM letter also expresses concern that the CPSC's statements of investigation will lead to unwarranted and unfair bad publicity, reduced sales, warranty claims, and lawsuits against the subject companies. The CPSC will not implement the new policy until it responds in writing to NAM's objections sometime this year.

Federal Court Finds CPSC's Decision to Publish Database Complaint Unlawful

The most momentous challenge to the CPSC's more aggressive oversight came from an anonymous company that brought suit against the CPSC in the U.S. District Court of Maryland for publishing a complaint in the CPSC database, over the company's objection that the complaint was "materially inaccurate." The CPSC database, launched in March 2011, allows the public to submit reports of harm involving a consumer product directly to a publicly searchable database. The district court opinion in *Company Doe v. Inez Tenenbaum*, No. 8:11-cv-02958-AW, U.S. Dist. LEXIS 153323 (D. Md. Oct. 16, 2012)—heavily redacted to ensure that the plaintiff could not be identified—sharply criticized the CPSC's review of the relevant incident report. The court explained that the CPSC's decision to publish the complaint was "arbitrary and capricious" and thus a violation of the Administrative Procedures Act because the evidence considered by the CPSC failed to link the consumer's alleged injury to the plaintiff manufacturer's product.

The decision, the first of its kind, highlights the concern that industry participants identified when the CPSC database was initially launched—that a lack of quality control over complaints submitted to the database would lead to misinformation being released to the public. There is no reliable way to verify the information submitted or to ensure that inaccurate information is excluded. It is also extremely expensive for wrongly accused companies, such as Company Doe, to litigate against the CPSC to remove incorrect complaints from their database.

The ruling in *Company Doe* may push the CPSC to more closely scrutinize complaints before publishing them to prevent further criticism from the courts. It may also give companies more leverage when challenging the accuracy of reports to be published in the database. The case is currently on appeal to the Fourth Circuit, even though the CPSC has dropped its appeal. Three consumer groups that intervened in the case are still pursuing the suit to press their position that the case should not be sealed to protect the identity of *Company Doe*.

LOOKING AHEAD TO 2013

Higher CPSC Civil Penalties in 2013?

Despite concerns in 2012 that CPSC fines would dramatically increase, they remained relatively unchanged in 2012 in comparison to previous years. (The 2012 penalties, against six companies, totaled $4.275 million with each penalty ranging from $400,000 to $1.5 million.) This was likely due to the settlement of cases before the statutory changes went into effect, and political gridlock among the two Democrats and two Republicans holding seats on the CPSC, which made it difficult to obtain the requisite majority vote for higher penalties.

We anticipate that penalties will increase in 2013, both in number and amount. The CPSC is now operating with three commissioners and a Democratic majority. Commissioner Adler indicated his desire to raise penalty amounts in his 2012 dissenting opinion regarding a $425,000 penalty against Hewlett-Packard (Adler wanted a steeper penalty). Companies facing reporting decisions should pay careful attention to the tide turning toward increasing penalties.

New Regulatory Requirements for Children's Products?

As of February 8, 2013, all importers and domestic manufacturers of children's products are required to maintain comprehensive technical files proving their products' continuing compliance with applicable CPSIA testing and certification rules. The new requirement means that, in addition to initial testing, importers and manufacturers must periodically test samples of continuing production to ensure that each product, throughout its lifespan, continues to meet applicable safety standards.

However, in October 2012, the CPSC had voted to direct agency staff to further investigate nine recommendations that would reduce the burden of the third-party testing under the 2013 rules. Given the ongoing "investigation," there is some uncertainty whether some of the regulations may be cut back. Even if some of the recommendations are implemented, 2013 will bring significant new burdens to manufacturers and importers of children's products.

Can Consumers Bring Claims for Items That They Never Purchased?

Courts are sorting out whether plaintiffs can bring claims for items that they never purchased. Two seemingly contrary California federal district court opinions illustrate the split in the courts. In *Miller v. Ghirardelli Chocolate Company*, No. 12-04936 LB, 2012 U.S. Dist. LEXIS 174008 (N.D. Cal. Dec. 7, 2012), a district court held that plaintiffs may have standing to assert claims for unnamed class members based on products that they did not actually purchase, but only if the products and the alleged misrepresentations were "substantially similar." The court ruled that the plaintiff in that case did not have standing to bring claims relating to dissimilar products (different chocolate products) that he did not purchase. Only three weeks later, in *Colucci v. ZonePerfect Nutrition Company*, No. 12-2907-SC, 2012 U.S. Dist. LEXIS 183050 (N.D. Cal. Dec. 28, 2012), the district court ruled that the plaintiff did have standing to challenge the labeling of the 19 different varieties of ZonePerfect bars, even though the plaintiff had only purchased one flavor, because the bars were similar enough.

We will continue to monitor these types of cases to analyze how courts view products that may be "substantially similar," and how such cases may impact class certification in consumer product cases.

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES
KEY MATTERS

We represent some of the world's most recognized pharmaceutical and medical-device companies, frequently serving as their national counsel in multiple jurisdictions. Our team includes talented trial lawyers with top-notch technical expertise, supported by more than 130 life sciences lawyers and 350 intellectual property experts. With this deep bench, we can address any challenge that our pharmaceutical and medical-device clients face.

EYE CARE
Represent a **large eye care product manufacturer** in several product liability lawsuits brought by plaintiffs claiming eye injuries from ophthalmic medical devices.

CONTACT LENSES
Serve as national coordinating counsel for a contact lens manufacturer in product liability cases that have been filed in several jurisdictions alleging that defective contact lenses caused injuries.

PAIN PUMP MATTERS
Served as national counsel for a large pharmaceutical company in nationwide pain pump litigation. These product liability cases alleged that local anesthetic products used in pain pumps led to postsurgical chondrolysis, a degenerative condition of the shoulder. Plaintiffs were young athletes claiming career-ending injuries. We **secured the dismissal of our client from 189 cases brought by 478 plaintiffs**, with no settlement payments through voluntary dismissals and successful motions to dismiss.

IN RE AREDIA AND ZOMETA LITIGATION
Represented a leading pharmaceutical manufacturer in an MDL proceeding and in state consolidated cases where plaintiffs claimed an injectable drug caused a degenerative condition of the jaw. The MDL included as many as 190 plaintiffs, who had sued manufacturers of pamidronate, the generic form of the bisphosphonate cancer treatment Aredia. We moved to dismiss the claims of the majority of plaintiffs based on their failure to identify which generic pamidronate product they allegedly had taken. Following the U.S. Supreme Court's ruling in *PLIVA v. Mensing*, a number of **plaintiffs agreed to voluntarily dismiss their claims with prejudice**, and we and the other defendants moved for summary judgment on the remainder. In January 2012, the court granted summary judgment on all remaining claims.

REGULATORY ADVISEMENT
Advise pharmaceutical and medical-device companies on a wide range of regulatory issues, including adverse event reporting, clinical trials, label and warning revisions, periodic submissions, and risk mitigation during the FDA approval process.

HEPARIN PRODUCTS LIABILITY LITIGATION
Serve as **national coordinating counsel in numerous cases filed around the United States** alleging side effects from heparin-induced thrombocytopenia. Fresenius Kabi is the largest manufacturer of heparin, a prescription injectable anticoagulant (blood thinner) often used in hemodialysis and cardiac invasive procedures.

PHARMACEUTICAL AND MEDICAL-DEVICE PRODUCT LIABILITY ADVISEMENT
Routinely advise pharmaceutical and medical-device companies on a variety of issues, including distribution, manufacturing, safety agreements, and product liability avoidance.

IN RE REGLAN/METOCLOPRAMIDE LITIGATION
Defend a large international pharmaceutical company in **hundreds of lawsuits (comprising more than 2,000 individual claims)** in which the plaintiffs allege that Reglan/metoclopramide, when prescribed off-label for psychiatric purposes, causes significant side effects and damages health. The cases are pending in mass tort proceedings in Pennsylvania, New Jersey, and California.

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES TRENDS

In 2012, courts tested the metes and bounds of the Supreme Court's landmark holding in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011). *Mensing* had held that failure-to-warn claims against generic pharmaceutical manufacturers were preempted due to federal requirements that generic drug labels be identical to that of the innovator, or brand-name, drug. It also left generic drug users with no clear remedy for product liability claims. The past year saw both proposed legislative and judicial response to *Mensing*, which we expect to continue through 2013. The coming year may also bring regulatory change, as recently announced by the FDA. Although these actions are directed at generic pharmaceutical manufacturers, we expect the push for increased liability to have a broader impact throughout the pharmaceutical and medical-device industry.

Early Successes for Generic Manufacturers in 2012

Mensing had enormous impact in early 2012, as generic manufacturers successfully obtained both voluntary and court-ordered dismissals of cases against generic companies. In January 2012, MoFo obtained a dismissal for our client in the pamidronate multidistrict litigation (MDL) when the court found the plaintiffs' claims preempted under *Mensing*. *In re: Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479 (E.D.N.Y. 2012). We also helped a client obtain dismissal from the New Jersey Reglan/metoclopramide litigation under *Mensing*. *In re Reglan Litig.*, No. 289, 2012 WL 1617417 (N.J. Super. Ct. May 4, 2012).

Other generic manufacturers had similar successes in 2012. In January, a generic manufacturer obtained a dismissal from the *Fosamax* MDL based on *Mensing*. *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, MDL No. 2243 (JAP-LHG), 2012 WL 181411 (D.N.J. Jan. 17, 2012). Courts around the country dismissed numerous cases against generic manufacturers of metoclopramide. *See, e.g.*, *Huck v. Trimark Physicians Grp.*, No. LACV018947, 2012 WL 553492 (Iowa Dist. Jan. 5, 2012); *Kellogg v. Wyeth*, No. 2:07-cv-82, 2012 WL 368658 (D. Vt. Feb. 3, 2012); *Moretti v. Mutual Pharm. Co.*, 852 F. Supp. 2d 1114 (D. Minn. 2012). By spring 2012, there was growing concern over the perceived inequality that the Supreme Court had created (patients who had been injured by a brand-name drug could sue, but those who had been injured by a generic drug could not), prompting complaints from consumer groups.

Undoing *Mensing*: Proposed Legislation

In response to these consumer groups, Sen. Patrick Leahy (D-Vt.) introduced legislation in April 2012 intended to undo *Mensing*. The bill—the Patient Safety and Generic Labeling Improvement Act—would have permitted generic manufacturers to change their labels to add or strengthen warnings in response to patient safety concerns. The bill also would have allowed the FDA to order label changes to ensure conformity among equivalent drugs. Although the bill died in committee, consumer advocacy groups will no doubt continue to pressure legislators and the FDA for change.

LOOKING AHEAD AT 2013

Working Around *Mensing*

Although a legislative response to *Mensing* likely remains in the distant future, we predict increasing litigation against both brand-name and generic manufacturers as plaintiffs strive to find causes of action that will survive *Mensing*'s preemption analysis. Regulatory change may also be around the corner. Four very recent developments provide a glimpse of what lies ahead.

Duty to Withdraw

At the end of November 2012, the Supreme Court granted certiorari in *Mutual Pharmaceutical Co. v. Bartlett*, No. 12-142 (on appeal from the U.S. Court of Appeals for the First Circuit, *Bartlett v. Mutual Pharm. Co.*, 678 F.3d 30 (1st Cir. 2012)). Plaintiff Karen Bartlett had won a $21 million verdict in federal district court in 2010 (pre-*Mensing*) against a manufacturer of generic sulindac based on design-defect claims. Defendant appealed, arguing that it could not be liable for design defect because it did not design the product. Instead, defendant urged that federal law required the generic drug's design to be the same as its brand-name equivalent, thereby preempting design-defect claims. The First Circuit upheld the verdict, finding that the manufacturer could have avoided liability by withdrawing its product from the market.

Now that the case is pending before the Supreme Court, industry groups are keeping close watch. Although the question in *Bartlett* is limited to design-defect claims, a "duty to withdraw" could easily apply to other causes of action, including failure to warn. Interested parties should keep an eye on the Court's demeanor during oral argument in March, and look for the Court's decision near the end of its term in June.

Duty to Warn the FDA

Another emerging cause of action is the "failure to warn the FDA." In January 2013, the U.S. Court of Appeals for the Ninth Circuit created this new state-law cause of action against medical-device manufacturers. *Stengel v. Medtronic Inc.*, __ F.3d __, 2013 WL 106144, 13 C.D.O.S. 365 (9th Cir. 2013). In *Stengel*, the plaintiff claimed that defendant's pain pump caused him to become a paraplegic. Plaintiff also alleged that the defendant became aware of risks associated with the pain pump before the incident but did not inform the FDA. In an en banc decision, the Ninth Circuit held that the defendant manufacturer could be found liable for failing to disclose adverse events to the FDA.

Stengel appears to fly in the face of long-standing precedent holding that federal law preempts claims of fraud against, and failure to report to, the FDA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Nevertheless, the Ninth Circuit insisted that plaintiffs could assert claims against defendant for failing to notify the FDA. This newly created "failure to warn the FDA" claim has potentially far-reaching consequences. It opens the door to claims against any defendant that has an obligation to report adverse events to the FDA, including not just medical-device companies but also brand-name and generic drug manufacturers. As such, this new claim could provide an avenue of relief for generic drug plaintiffs seeking to circumvent *Mensing* preemption.

Innovator Liability for Generic Drugs

The most recent decision affirming expansion of liability against drug manufacturers came in January 2013, when Alabama became the first state whose highest court adopted brand-name manufacturer liability for a generic drug sold by another company. *Wyeth, Inc. v. Weeks*, No. 1101397 (Ala. Jan. 11, 2013). There, the brand-name defendant had argued in federal district court that it could not be liable to the plaintiff because it had not sold or manufactured the drug in question. The district court certified the state-law question to the Alabama Supreme Court. In a surprising decision, the Alabama Supreme Court held that the brand-name manufacturer could be liable for failure to warn.

The Alabama court recognized that it was adopting the minority view. However, it was not the first court to reach this conclusion, and it relied on the reasoning articulated by the California Court of Appeals in *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89. The *Conte* court found that because the generic label was required to be identical to the brand-name label, it was entirely foreseeable that a physician would rely on the brand-name drug's warning in prescribing a generic drug. It was also foreseeable that the pharmacist would substitute the generic as permitted or required by state law or insurance, even if the brand-name drug had originally been prescribed. Because such reliance is foreseeable, "it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce."

Weeks remains the minority view, and the defendant has petitioned for reconsideration. However, *Weeks* is currently the law of Alabama and provides generic drug users with another cause of action on which to anchor their claims in the wake of *Mensing*.

Regulatory Change Ahead?

While courts try to sift through these issues, the FDA maintains the authority to effect regulatory change in response to *Mensing*, and has recently announced that it is considering doing just that. The first hint of this appeared in a footnote in the Department of Justice's amicus brief filed with the Supreme Court in support of the pharmaceutical manufacturer in *Bartlett*. Just a few weeks later, the FDA announced that regulatory changes may be coming that would allow generic manufacturers to change their labels independently of the brand-name manufacturers. The FDA has not yet published a proposed rule in the Federal Register, but industry and consumer groups are likely to voice their comments promptly and prominently. We expect at least minor regulatory changes in the next couple of years as the FDA attempts to satisfy consumer groups demanding a response to *Mensing*.

Staying Ahead of the Curve

The plaintiffs' bar will continue to devise new causes of action for pharmaceutical and medical-device litigation, with or without regulatory and legislative changes. MoFo's Product Liability Group not only defends current cases brought against our clients, but monitors new developments in the law to best minimize the risk of future litigation. This includes working with clients throughout their product-development cycle, assessing their risk, working with regulators, developing warnings, litigating, and taking issues up on appeal.

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Best Lawyers recognized 14 of our partners: Michèle Corash, Grant Esposito, Robert Falk, Arturo González, Adam Hoffinger, Peter Hsiao, James Huston, William O'Connor, Dennis Orr, Charles Patterson, Penelope Preovolos, Don Rushing, Michael Steel, and William Stern.

The Daily Journal recognized Erin Bosman as one of the "Top Women Lawyers" in California.

The Daily Journal recognized Arturo González as one of the "Top 100 Leading Lawyers" in California.

Best Lawyers named Don Rushing "San Diego Product Liability Lawyer of the Year."

Benchmark Litigation recognized James Huston and Don Rushing as Product Liability "Litigation Stars" in California.

Erin Bosman was nominated by in-house counsel as one of the outstanding practitioners in her field in the *Guide to the World's Leading Women in Business Law*.

James Huston was selected as a Fellow in the Litigation Counsel of America's Trial Lawyer Honorary Society.

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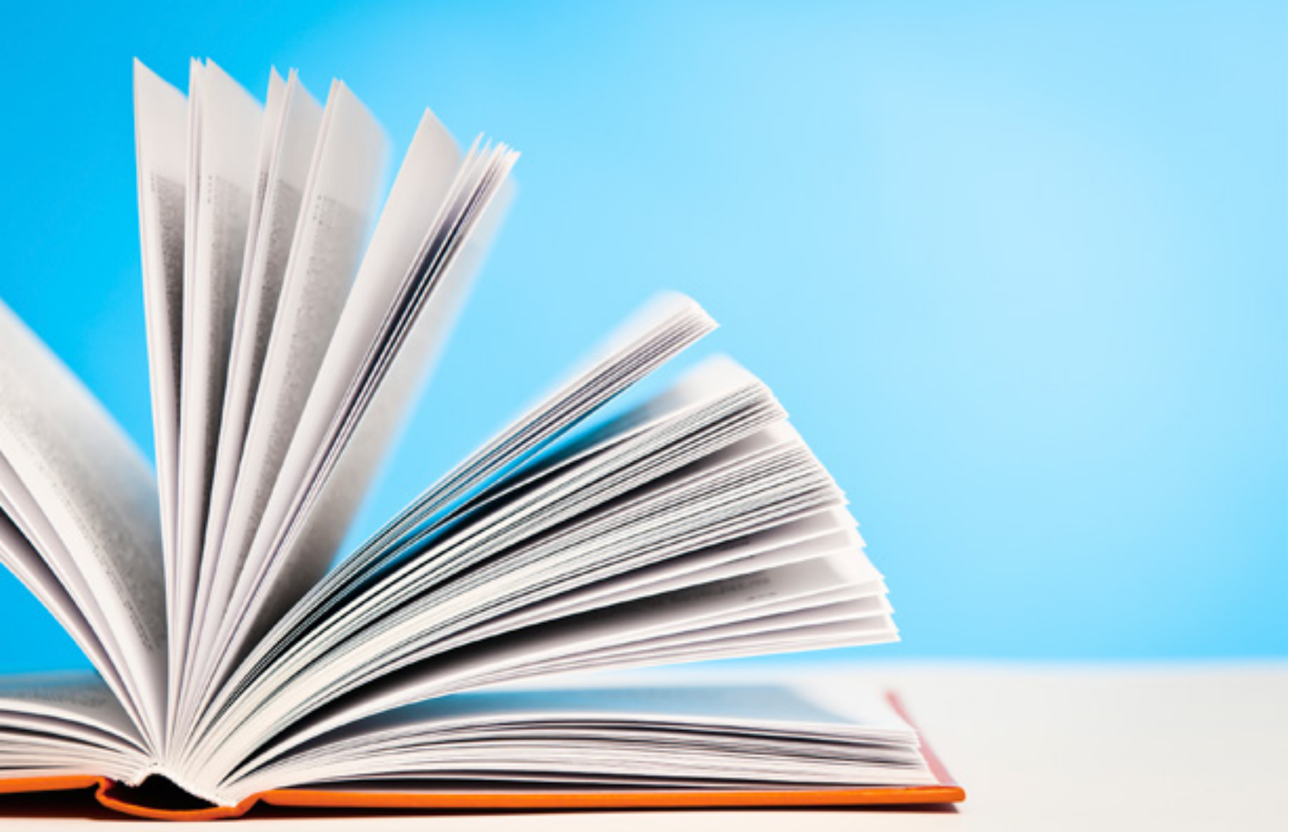

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KEY CONTACTS

James Bergin
Partner, New York
(212) 468-8033
jbergin@mofo.com

Erin Bosman (Chair)
Partner, San Diego
(858) 720-5178
ebosman@mofo.com

Michèle Corash
Partner, San Francisco
(415) 268-7124
mcorash@mofo.com

Robert Falk
Partner, San Francisco
(415) 268-6294
rfalk@mofo.com

David Fioccola
Partner, New York
(212) 336-4069
dfioccola@mofo.com

Grant Esposito
Partner, New York
(212) 468-8166
gesposito@mofo.com

Arturo González
Partner, San Francisco
(415) 268-7020
agonzalez@mofo.com

Adam Hoffinger
Partner, Washington, D.C.
(202) 887-6924
ahoffinger@mofo.com

Peter Hsiao
Partner, Los Angeles
(213) 892-5731
phsiao@mofo.com

James Huston
Partner, San Diego
(858) 720-5154
jhuston@mofo.com

William Janicki
Of Counsel, San Diego
(858) 720-5195
wjanicki@mofo.com

Rebekah Kaufman
Partner, San Francisco
(415) 268-6148
rkaufman@mofo.com

Charles Kerr
Partner,New York
(212) 468-8043
ckerr@mofo.com

Linda Lane
Partner, San Diego
(858) 720-7989
llane@mofo.com

Daniel Levison
Partner, Tokyo
011 81 3 3214 6717
dlevison@mofo.com

David McDowell
Partner, Los Angeles
(213) 892-5383
dmcdowell@mofo.com

Andrew Muhlbach
Partner, San Francisco
(415) 268-7221
amuhlbach@mofo.com

William O'Connor
Partner, San Diego
(858) 720-7932
woconnor@mofo.com

Dennis Orr
Partner, New York
(212) 468-8161
dorr@mofo.com

Charles Patterson
Senior Counsel, Los Angeles
(213) 892-5553
cpatterson@mofo.com

Penelope Preovolos
Partner, San Francisco
(415) 268-7187
ppreovolos@mofo.com

Don Rushing
Partner, San Diego
(858) 720-5145
drushing@mofo.com

James Schurz
Partner, San Francisco
(415) 268-6449
jschurz@mofo.com

Robin Stafford
Of Counsel, San Francisco
(415) 268-6674
rstafford@mofo.com

Michael Steel
Partner, San Francisco
(415) 268-7350
msteel@mofo.com

William Stern
Partner, San Francisco
(415) 268-7637
wstern@mofo.com

William Tarantino
Partner, San Francisco
(415) 268-6358
wtarantino@mofo.com

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