Shook, Hardy & Bacon L.L.P.

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PRODUCT LIABILITY LITIGATION REPORT

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FIRM NEWS

Newstead Compares US and UK Approaches to Medical Apps

Shook, Hardy & Bacon Global Product Liability Partner **Alison Newstead** has **authored** an article titled "Healthcare apps: comparing the US and UK approaches" appearing in the April 2014 issue of *The In-House Lawyer*. According to U.S. Food and Drug Administration (FDA) guidance issued in September 2013, that agency will, in Newstead's view, take a "pragmatic, hands-off, risk-based approach" to regulating medical applications (apps) as medical devices, focusing on functionality and evaluating "whether the app could pose a risk to patient safety if it did not function as intended."

The U.K.'s Medicines and Products Healthcare Regulatory Agency (MHRA), while taking a similar approach to defining what constitutes a medical app in its March 2014 guidance, will focus on the app's intended purpose. In this regard, MHRA will assess the medical apps' purpose "in light of all claims made in relation to the app, including claims made in promotional material such as brochures and webpages." Despite the "striking similarities, between the two sets of guidelines," Newstead writes, "the UK regulator has not gone as far as the US FDA in terms of 'enforcement discretion.'… US developers should therefore beware as these apps which may not attract attention in the USA may do so in the UK."

CASE NOTES

SCOTUS to Review CAFA Removal Requirements

The U.S. Supreme Court (SCOTUS) has decided to review a lower court decision involving the evidence required of defendants filing a notice to remove a lawsuit brought in state court to federal court under the Class Action Fairness Act of 2005 (CAFA). *Dart Cherokee Basin v. Owens*, No. 13-719 (U.S., cert. granted April 7, 2014). The issue arises in the context of a putative class action seeking royalty payments under certain Kansas oil and gas leases.

According to the defendant petitioners, the Tenth Circuit Court of Appeals let stand an order remanding the case to state court on the district court's refusal to consider evidence establishing federal jurisdiction under CAFA—the $5-million amount-in-controversy requirement—because that evidence was not attached to the

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removal notice. The petitioners contend that 29 U.S.C. §1446(a) requires only that a defendant seeking removal file a notice containing "a short and plain statement of the grounds for removal" and attach the state court filings served on the defendant. They argue that seven sister circuit courts of appeals "do not require the defendant to attach evidence supporting federal jurisdiction to the notice of removal. District courts in those Circuits may consider evidence supporting removal even it if comes later in response to a motion to remand."

Ninth Circuit Rules on Expert Causation Evidence in Bisphosphonate Treatment Injury Case

The Ninth Circuit Court of Appeals has determined that a district court erred in excluding the causation testimony of the plaintiff's expert as irrelevant and unreliable in a lawsuit alleging that bisphosphonate treatment caused her to develop osteonecrosis of the jaw (ONJ). ***Messick v. Novartis Pharms. Corp.*, No. 13-15433 (9th Cir., decided April 4, 2014)**. The plaintiff's breast-cancer treatment, including chemotherapy and steroid therapy, led to the development of osteoporosis. She was treated with bisphosphonate to address that condition and was later diagnosed with osteonecrosis of the jaw (ONJ). It eventually healed, and she sued the manufacturer.

According to the court, the lower court applied too high a relevancy bar under California law and, because the plaintiff's expert said that her use of bisphosphonate was a "substantial factor" in the development of ONJ, "his testimony is relevant." The court also faulted the lower court for excluding the testimony because the expert "never explained the scientific basis for this conclusion"—i.e., that "a patient without cancer or exposure to radiation in the mouth area would not develop ONJ lasting for years without IV bisphosphonate treatments."

The court found it sufficient that the expert, board certified in oral maxillofacial surgery, had extensive clinical experience and relied on the American Association of Oral and Maxillofacial Surgeons definition of bisphosphonate-related ONJ in reaching his diagnosis and causation conclusions. Given inherent uncertainties in establishing a medical cause-and-effect relationship, the court found it sufficient that a medical condition be a "substantial causative factor." The Ninth Circuit held that the district court abused in discretion in excluding the testimony "when it found that testimony to be unreliable largely because Dr. Jackson could not 'determine in a patient who has multiple risk factors at one time which of those particular risk factors is causing [the ONJ].' Such an unduly exacting standard goes beyond the district court's proper gatekeeping role." Accordingly, the court reversed the grant of summary judgment and remanded for further proceedings.

Individual Cases Severed from CAFA Class May Retain Federal Jurisdiction

The Fifth Circuit Court of Appeals has held that claims severed from a Class Action Fairness Act (CAFA) case retain federal jurisdiction if the class-action lawsuit had original, rather than supplemental, jurisdiction when removed to federal court. ***Louisiana v.***

Am. Nat'l Prop. & Cas. Co., No. 14-30071 (5th Cir., decided March 26, 2014). The court refused to apply the *Honeywell* exception to the general rule that "jurisdictional facts are determined at the time of removal, not by subsequent events." That exception would have required each severed action to have an independent jurisdictional basis to remain in federal court.

The decision was part of the ongoing "Road Home Litigation" involving a Louisiana program that required Hurricane Katrina victims to assign their insurance policies to the state in exchange for immediate funds to rebuild damaged homes. Louisiana then filed a class action to recover from the insurance companies, which petitioned to remove the case to federal court with subject matter jurisdiction supplied by CAFA. After certifying a question to the Louisiana Supreme Court, the district court severed the individual claims from the class action and directed the state to file amended complaints for each claim. The district court, and later the Fifth Circuit, then addressed whether the individual claims should remain in federal court.

Generally, post-removal events do not affect properly established jurisdiction. Under an exception established in *Honeywell Int'l, Inc. v. Phillips Petroleum Co.*, 415 F.2d 429 (5th Cir. 2005), however, "an action severed from the original case must have an independent jurisdictional basis, which in turn calls for jurisdictional facts to be determined post-removal, at the time of severance." Granting the insurance companies' request for the litigation to remain in federal court, the Fifth Circuit pointed to *Honeywell's* facts, its subsequent citations and CAFA's text and legislative history to determine that *Honeywell* applies only to "claims that were never infused with original jurisdiction, but state claims that were tagging along in the tail wind of the original federal claims."

Accordingly, supplemental jurisdiction as the basis for removal to federal court may later be grounds for a new jurisdiction determination after severance, but cases granted original jurisdiction then later severed may not be remanded to state court under the *Honeywell* exception.

NY High Court Affirms $8.8 Million Verdict in Post-Hole Digger Design-Defect Suit

The New York Court of Appeals, the state's highest court, has affirmed an $8.8 million judgment rendered against companies that made and sold a post-hole digger and its component parts that allegedly caused a teenager's personal injuries, including the loss of most of her right arm. *Hoover v. New Holland N. Am., Inc.*, No. 36 (N.Y., decided April 1, 2014). The defendant companies argued on appeal that the trial court erred by refusing to grant their motion for summary judgment as to the plaintiffs' design-defect claims. The Court of Appeals agreed with the lower court that, while the defendants "met their initial burden on their motion for summary judgment," the plaintiffs "submitted sufficient evidence to defeat that motion and on their direct case at trial to make out a prima facie case of defective design of the digger."

The digger's owner was a grape farmer who used it to drill 1,000 to 2,000 post holes annually for about four years before he removed a plastic shield that covered a protruding nut-and-bolt assembly which evidence showed had caught on the teenager's jacket pocket. He removed the shield because his use of the digger brought the shield into contact with the ground at least 5 to 10 percent of the time, damaging the shield beyond repair. The farmer testified that he decided not to replace it because he knew it would become "bent up, broke up, and tore off again." The digger was lacking the shield when the teenager's stepfather borrowed and used it.

The digger's on-product warnings and owner's manual warned against operation without all equipment shields in place and told the operator not to allow it to penetrate the ground to a depth where the helical blade would be submerged—this is what occurred every time the shield made ground contact. The defendants argued that they should not be held liable because they had designed and produced a safe product, and the injuries resulted from "substantial alterations or modification of the product by a third party."

The defendants argued that they should not be held liable because they had designed and produced a safe product, and the injuries resulted from "substantial alterations or modification of the product by a third party."

The high court majority stated that the grape farmer's failure to replace the broken safety shield did not entitle the defendants to summary judgment because "expert evidence raised a question whether Smith's failure to replace the shield alone caused plaintiff's injuries, or whether his failure pointed to a failure on defendants' part in selling and distributing the digger with a defectively designed shield.… Although owners are obligated to keep their products in good repair, they should not be required to continually replace defective safety components even if, as here, the components could be replaced easily and cheaply."

According to the court, the defendants did not show that the owner's use constituted abuse of the digger—"[u]sing the digger to drill thousands of post holes per year appears to fall squarely within the intended use of that product, and nothing in the record conclusively shows at what point a properly designed shield would be expected to wear out and require replacement under these circumstances." The court also pointed to evidence that ground contact was foreseeable during normal use and that "more robust durability testing would have revealed that a plastic shield would not hold up under these circumstances. Indeed, the record indicates that the shield underwent limited durability testing, none of which included contact with the ground."

The lone dissenting judge characterized the case as the "kind of soak-the-rich fact-finding" that "is commonplace in American tort law." This jurist would have ruled that the post-hole digger was safe at the time of sale and that it "would have remained in place if Smith had not battered it into uselessness, thrown it away and not bothered to replace it."

Pa. Supreme Court Declines Review of Asbestos Rulings

The Pennsylvania Supreme Court has reportedly decided not to review two asbestos-exposure cases that purportedly produced opposing conclusions in the intermediate appellate court as to the admissibility of expert testimony on an "any-exposure" causation theory. In *Nelson v. Airco Welders Supply*, a divided three-judge intermediate appellate court panel reversed a $14.5 million verdict, finding the plaintiff-expert's causation testimony inadmissible, and granted a new trial. The court has since granted reargument before the full court. Immediately after the verdict was reversed, however, a different superior court panel unanimously affirmed a judgment against Hobart Brothers Co.—a defendant in *Nelson*—in a different case involving the same issue and the same plaintiff's expert (*Campbell v. Hobart Brothers*), finding that his testimony did not violate the any-exposure theories established in *Betz v. Pneumo Abex*.

The company's King's Bench petition to the state supreme court stated, "Only swift and decisive review by this court of both *Nelson* and *Campbell* can ensure this court's prior rulings are followed consistently by the lower courts." Plaintiff Darlene Nelson reportedly argued that her expert did not rely on an "every fiber" or any-exposure causation theory, because her deceased husband was exposed to asbestos on a daily basis for three years. She also said that the defendants failed to show that an issue of immediate importance warranted the supreme court's review. "It was not until after the Superior Court granted reargument en banc that defendants decided the normal appellate process was too slow," she said. The supreme court denied the petition on April 3, 2014. *See The Legal Intelligencer*, April 7, 2014.

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Four Loko Maker Settles AG Claims

According to New York Attorney General (AG) Eric Schneiderman, Phusion Projects, LLC, the company that makes Four Loko flavored malt beverages, has agreed to settle allegations by 20 attorneys general and the San Francisco city attorney that the company marketed and sold its products in violation of consumer protection and trade practice statutes. *In re Investigation by Eric T. Schneiderman, N.Y. AG of Phusion Projects, LLC*, No. AOD 14-075 (N.Y. AG, Bureau of Consumer Frauds & Protection, March 25, 2014).

Without admitting any liability, the company has agreed not to (i) promote the misuse of alcohol or mixing flavored malt beverages with caffeinated products; (ii) manufacture, market, sell, or distribute any caffeinated alcohol beverages; (iii) provide materials to wholesalers, distributors or retailers promoting mixing flavored malt beverages with caffeinated products; (iv) sell, distribute or promote alcohol beverages to underage persons or hire underage persons to promote these products; (v) use college-related logos to promote its products; or (vi) use Santa Claus in its promotional materials. The company also agreed to monitor social media and remove any postings depicting the consumption of caffeinated alcohol beverages or condoning the misuse of alcohol.

The company will pay $400,000 to cover attorney's fees, costs and consumer education programs or for other purposes at the AG and city attorney's discretion. *See AG Eric Schneiderman Press Release*, March 25, 2014.

THE INTERNATIONAL BEAT

Class Action Device Adopted in France

President François Hollande has signed into law France's new Consumer Law, which includes a class action procedure for consumer protection and antitrust claims. While the law took effect when signed on March 19, 2014, this procedure is not immediately effective. It has survived a Constitutional Council review, and the government has already indicated that it wishes to extend the model to health and environmental claims. Additional details about the class-action provisions appear in Shook, Hardy & Bacon's **April 2014** *International Class Action Update.*.

The class-action provisions will not take effect until the implementation decree is published, which is expected this summer. The decree will provide more technical information about the law's operation and interpretation. For example, in its current form, the law provides little guidance for courts about the criteria to apply in determining whether a claim is appropriate for class resolution. Other statutory requirements include limiting standing to bring class actions to officially recognized consumer associations, providing recovery only for pecuniary damages for injuries allegedly caused by a breach of contract or statutory duty in connection with the sale of goods or supply of services, and establishing a two-phase proceeding. A court will first decide general liability as to representative plaintiffs and then certify the class. After appeals are exhausted, absent class members are notified during the second phase, and they have the opportunity to opt in and enforce their claim by providing evidence of class membership.

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ALL THINGS LEGISLATIVE AND REGULATORY

Senate Committee Holds Nomination Hearing on New CPSC Chair

The U.S. Senate Committee on Commerce, Science, and Transportation held an April 8, 2014, hearing to consider the nominations of Elliot Kaye (D) and Joseph Mohorovic (R) to the Consumer Product Safety Commission (CPSC). Currently serving as the agency's executive director, Kaye was tapped on March 28 by President Barack Obama to serve as CPSC chair. If confirmed, Kaye will fill the vacancy left by Inez Tenenbaum, whose four-year term as chair ended in November 2013. Kaye is known for playing a key role in advancing Tenenbaum's efforts to reduce brain injuries in youth sports, prevent deaths and serious burn injuries to children from the ingestion of coin cell batteries, and combat deaths and injuries from carbon monoxide poisoning.

Kaye was joined by nominee Joe Mohorovic, named by the president in November 2013 to fill the seat vacated by Nancy Nord (R). Because no party can have more than three commissioners at any time, Mohorovic's nomination has been on hold until the Obama administration could pair him with a Democratic chair nominee. Mohorovic served as a senior CPSC staff member for several years, including as chief of staff to former commission Chair Hal Stratton, before entering the private sector. *See cpscmonmitor.com*, April 7, 2014.

ALJ Rules Buckyballs CEO Not Required to Produce Personal Financial Information

An administrative law judge (ALJ) has determined that the former CEO of a company that sold high-power magnet desk toys subject to a hazardous-product proceeding before the U.S. Consumer Product Safety Commission (CPSC) is not required to produce information about his personal finances. *In re Maxfield & Oberton Holdings, LLC*, CPSC Docket Nos. 12-1, -2, 12-2 (CPSC, order entered March 26, 2014).

Craig Zucker had sought a protective order as to his financial information and that of the now-defunct corporation. He argued that CPSC was "conflating the concepts of the responsible officer doctrine with an attempt to pierce the corporate veil and make Mr. Zucker the alter ego of the company." CPSC claimed that it needed the information because it would be relevant to a remedy in the case. The ALJ disagreed as to Zucker's personal information, stating that the law "does not, as alleged, required the undersigned to consider finances when determining an appropriate remedy.… [and] CPSC does not explain how a company's insufficient funds would create a 'charge' for a person wishing to avail themselves of a financially unfeasible remedy."

Regarding CPSC's claim that "if the undersigned determines the subject magnets constitute a substantial product hazard, Mr. Zucker should be responsible for any ordered remedy by virtue of the responsible corporate officer doctrine," the ALJ determined that company-related financial information may be relevant, but that "CPSC has failed to demonstrate how or why financial items related solely to Mr. Zucker should be discoverable."

CPSC to Settle Claims in Drawstring Violation Case for $600,000

The U.S. Consumer Product Safety Commission (CPSC) has **requested** comments on whether the commission should accept a provisional settlement with Forman Mills, Inc., which has agreed to pay a $600,000 civil penalty to settle claims that it violated the law by selling children's upper outerwear garments with drawstrings. According to the agreement, the company had previously been fined for failing to report that it had distributed such garments in commerce. It has also agreed to adopt policies that will reduce the possibility that these products will be sold again through its stores. Comments are requested by April 15, 2014. *See Federal Register*, March 31, 2014.

CPSC Issues Final Rule for Soft Infant Carriers

The U.S. Consumer Product Safety Commission (CPSC) has **issued** a final rule, effective September 29, 2014, adopting a voluntary industry standard for soft infant and toddler carriers.

Defining such carriers as wearable, fabric products designed to carry a full-term infant or toddler upright and close to the caregiver, the agency notes that the new standard addresses several falling-related and other safety hazards associated with the products, including fastener problems, large leg openings, stitching and seam problems, and slippery straps. Between September 11, 2012, and July 15, 2013, the agency received 31 infant-carrier related incident reports, including two fatalities. *See Federal Register*, March 28, 2014.

NHTSA Issues Final Rule on Backup Cameras in New Vehicles

The U.S. National Highway Traffic Safety Administration (NHTSA) has **issued** a final rule that will require rearview cameras on all new cars, trucks and buses weighing less than 10,000 pounds.

The rule aims to reduce the risk of backover crashes involving vulnerable populations (children, the elderly and persons with disabilities) and satisfy the mandate of the Cameron Gulbransen Kids Transportation Safety Act of 2007 directing the agency to improve rear-visibility technology in new vehicles.

With an anticipated two-year phase-in scheduled to begin in May 2016, the rule will require that the camera's field of view cover a 10-foot-by-20-foot zone directly behind the vehicle. The system must also meet other requirements, including image size, linger time, response time, durability, and deactivation. NHTSA estimates that approximately 70 lives will be saved each year once all new vehicles comply with the rule. *See Federal Register,* April 7, 2014.

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EPA Orders Halt to Sales of Food Storage Products

The U.S. Environmental Protection Agency (EPA) has issued a stop sale, use or removal order against New Jersey-based Pathway Investment Corp. concerning company food storage products containing nano silver. According to the agency, these products—Kinetic Go Green Premium food storage containers, Kinetic Smartwist Series containers, TRITAN food storage, and StackSmart Storage—are marketed "as containing nano silver, which the company claims helps reduce the growth of mold, fungus and bacteria." As such the products contain pesticides and must be registered under the Federal Insecticide, Fungicide and Rodenticide Act. These products were not registered and were not subjected to efficacy testing. EPA has also notified retailers that have sold the products on their Websites to cease doing so. *See EPA News Release*, March 31, 2014.

LEGAL LITERATURE REVIEW

Dana Remus & Adam Zimmerman, "The Corporate Settlement Mill," *Virginia Law Review* (forthcoming 2015)

University of North Carolina and Loyola Law School professors have authored an article describing how "corporate settlement mills" have joined other forms of mass dispute resolution—class actions, mandatory arbitration and aggregate litigation—"to achieve economies of scale in resolving high volumes of claims quickly, efficiently, and predictably." These private settlement systems, sometimes required of corporate defendants by state actors—for example, the Oil Pollution Act of 1990 required BP to establish its own claim facilities to automatically reimburse claims for damages in the Gulf of Mexico—offer promise as a litigation alternative, but raise questions of accountability, transparency and the potential for coercion.

The authors offer proposals for reform, including (i) consumer or other stakeholder participation in corporate settlement system design, (ii) "more comprehensive prospective administrative regulation for the operation of corporate settlement systems," (iii) revised ethical standards for lawyers designing the systems, and (iv) "enhanced judicial review of liability waivers acquired through these systems."

Nicholas Fromherz & Joseph Mead, "Choosing a Court to Review the Executive," *Administrative Law Review* (forthcoming 2014)

Lewis & Clark Law School and Cleveland State University professors explore the factors to be used when assessing which courts should have jurisdiction over lawsuits that challenge agency action. Observing that Congress has experimented for more than 100 years with agency review by district courts and circuit courts, the authors contends that the result is "a jurisdictional maze that varies unpredictably across and within statutes and agencies." They call for a "single system of judicial review that begins in the district court" as well as "greater attention to the manner in which district courts apply procedural rules to APA [Administrative Procedure Act] cases."

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LAW BLOG ROUNDUP

Civil Rules Changes Take Next Steps

"The next step in the process is a meeting of the Civil Rules Advisory Committee that will take place on April 10-11 in Portland, Oregon. As covered earlier, the agenda book for that meeting has now been posted on the US Courts website and is available here. At this meeting, the Civil Rules Committee will make recommendations to the Standing Committee, which will meet at the end of May." Seton Hall University School of Law Professor Adam Steinman, blogging about the most recent developments in

proposed changes to the Federal Rules of Civil Procedure. According to Steinman, the subcommittee has recommended withdrawing amendments that would place certain limits on discovery—i.e., lowering the presumptive numbers of depositions and interrogatories, limiting the presumptive number of requests to admit and reducing the presumptive length of depositions—while also recommending moving forward with changes that would amend the scope of discovery under Rule 26(b).

Civil Procedure & Federal Courts Blog, April 3, 2014.

THE FINAL WORD

Differences Between Shareholder-Speak and Consumer-Speak

Based on a doctoral dissertation, a recent article posits that consumers are as deserving of "informational accountability" as potential buyers of corporate securities. According to Shlomit Azgad-Tromer of Tel Aviv University—Buchmann Faculty of Law, "Corporations offering merchandise or services to the public, in 2014, enjoy the status of small merchants in the archaic marketplace: they need to provide consumers with information only to the extent where lack thereof would render the agreement involuntary, as required under contract law. Consumers of securities, on the other hand, are labeled 'investors,' and are considered prominent corporate stakeholders. Offering securities to the public entails an informational regime that includes periodic and immediate uniform disclosures including all material in plain English, accompanied by standardized financial audit and report." Azgad-Tromer calls for "setting positive disclosure standards on corporations offering products or services to the public," including materiality, accessibility and succinctness. *See The Harvard Law School Forum on Corporate Governance and Financial Regulation*, April 3, 2014.

UPCOMING CONFERENCES AND SEMINARS

Dunne to Address Mobile Medical Apps at FDLI Event

Shook, Hardy & Bacon Life Sciences & Biotechnology Partner **Debra Dunne** will join a distinguished faculty, including U.S. Supreme Court Justice Samuel Alito—the keynote luncheon speaker, during the Food and Drug Law Institute's (FDLI's) **Annual Conference**, April 23-24, 2014, in Washington, D.C. Dunne will serve on a panel addressing "Mobile Medical Apps and Unique Device Identifiers: Regulatory and Business Challenges."

Kaplan & Woodbury Join Faculty at DRI Drug and Medical Device Seminar

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partners **Harvey Kaplan** and **Marie Woodbury** will participate in DRI's "**Drug and Medical Device Seminar**" slated for May 15-16, 2014, in Washington, D.C. Kaplan will serve as the

moderator of a panel of judges discussing "Mass Tort Coordination Between Federal and State Jurisdiction," while Woodbury will serve on a panel demonstrating "Trial Skills: Warnings, Experts, and General Causation."

ACI, Chicago, Illinois – June 4-5, 2014 – "7th Annual Summit on Defending & Managing Automotive Product Liability Litigation." Shook, Hardy & Bacon Tort Partner H. Grant Law will participate in a panel discussion during this continuing legal education summit, which features presentations by judges as well as corporate and agency in-house counsel. His topic is "The Current Battleground for Automotive Class Action Litigation: Class Certification and Managing Experts, Attacks on Pleadings in Class Claims, Choice of Law, Arbitration and More." ■

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ABOUT SHB

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys have unparalleled experience in organizing defense strategies, developing defense themes and trying high-profile cases. The firm is enormously proud of its track record for achieving favorable results for clients under the most contentious circumstances in both federal and state courts.

The firm's clients include many large multinational companies in the tobacco, pharmaceutical, medical device, automotive, chemical, food and beverage, oil and gas, telecommunications, agricultural, and retail industries.

With 95 percent of our more than 440 lawyers focused on litigation, Shook has the highest concentration of litigation attorneys among those firms listed on the *AmLaw* ***100,*** *The American Lawyer's* list of the largest firms in the United States (by revenue).