

**PRODUCT LIABILITY
LITIGATION
REPORT**



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LOUISIANA AG FILES LAWSUIT AGAINST MAKERS AND IMPORTERS OF CHINESE DRYWALL

Louisiana Attorney General (AG) James (Buddy) Caldwell has filed litigation against Chinese and U.S. companies that made, imported or installed allegedly defective drywall in many homes and state buildings affected by hurricanes Katrina and Rita. [*Louisiana v. Knauf Gips KG, No. 2010-392 \(Parish of Orleans Civ. Dist. Ct., La., filed January 13, 2010\).*](#)

According to the petition, the “defective drywall is off-gassing various dangerous gases, including formaldehyde, hydrogen sulfide and carbonyl sulfide” and has been made “with waste material from scrubbers on coal-fired power plants.” The AG alleges that these chemicals cause respiratory problems, headaches, heart disease, neuron-behavioral problems, infections, and allergic reactions. The petition also contends that the “defective drywall is corroding or pitting electrical equipment,” which “can cause electric failures and property damage.”

Specifying particular shipments of drywall, warranted as of good quality and free from defects, into Louisiana ports, the petition alleges a broad array of expenses incurred by the state, its local subdivisions and citizens. They range from the remediation of state buildings to the costs of providing medical treatment to eligible citizens under Medicare and Medicaid. The petition alleges redhibitory vices, violations of the state’s unfair trade practices and products liability laws, breach of warranties, negligence, fraudulent concealment, fraudulent and negligent misrepresentation, and unjust enrichment. The state seeks compensatory, treble and punitive damages, as well as the “cost of disposing and waste monitoring of Defendants’ defective drywall,” costs, attorney’s fees, and interest.

MDL COURT DENIES MOTIONS TO DISMISS CLAIMS IN CHINESE DRYWALL LITIGATION

The multidistrict litigation (MDL) court currently presiding over claims filed in a number of federal courts over allegedly defective Chinese manufactured drywall has denied motions to dismiss some of the plaintiffs’ claims under the economic loss rule. *In re: Chinese Manufactured Drywall Prods. Liab. Litig.*, MDL No. 2047 (U.S. Dist. Ct., E.D. La., decided January 13, 2010). The distributor defendants sought to dismiss

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claims for economic damages, contending that the economic loss rules of the states where the claims originated do not allow recovery in tort for damage to property. The manufacturer defendants also sought to dismiss these claims, arguing that the economic loss rules apply to “manufacturers and distributors in the same way in all jurisdictions.”

The plaintiffs countered that economic loss rules are intended “to prevent plaintiffs from receiving tort remedies as a result of disappointed economic expectations and circumventing the contractual bargain they struck when allocating foreseeable risks.” According to the plaintiffs, this dispute far exceeds these concerns by presenting “the unprecedented failure of a product which is alleged to be causing a serious risk of hazard to safety and health, a classic case to which tort remedies apply.” The court discusses analogous cases under Alabama, Florida, Louisiana, and Mississippi law and, relying on federal and state court decisions involving asbestos building products, concludes that the claims are not barred by the economic loss rule.

FIFTH CIRCUIT JOINS EIGHTH TO FIND FEDERAL LAW DOES NOT PREEMPT STATE CLAIMS AGAINST GENERIC DRUG MAKERS

The Fifth Circuit Court of Appeals has determined that the U.S. Supreme Court’s name-brand drug preemption ruling in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), applies as well to state-law failure-to-warn claims against generic drug manufacturers. [*Demahy v. Actavis, Inc., No. 08-31204 \(5th Cir., decided January 8, 2010\).*](#)

The pharmaceutical involved was a generic form of Reglan®, prescribed for gastroesophageal reflux, which allegedly caused the plaintiff’s tardive dyskinesia, a neurological movement disorder. According to the court, the question whether federal law preempts the imposition of conflicting state law duties on those who manufacture the generic equivalents of name-brand drugs has divided the district courts. The Eighth Circuit Court of Appeals, however, has determined that state law is not preempted, a conclusion with which the Fifth Circuit agreed.

The defendant contended that *Levine* should not apply to generic manufacturers because, although name-brand manufacturers may change a label in advance of FDA approval through the “changes being effected” process, “federal law requires that [generic manufacturers] maintain at all times a label that is the ‘same as’ the name brand’s, thus preventing simultaneous compliance with a state law requiring additional warnings.”

The Fifth Circuit disagreed, noting that although federal law requires that the generic product contain labeling that is the “same as” that of the name-brand drug at the time of approval, plaintiff’s failure-to-warn claim was based on a failure to change the label *after* approval. “And, while Congress plainly intended for a generic drug manufacturer to submit labeling identical to—or, the ‘same as’—the brand

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name drug when seeking ANDA [abbreviated new drug application] approval, the statutory scheme is silent as to the manufacturer's obligations after the ANDA is granted."

The court also concluded that, just like name-brand manufacturers, generic manufacturers have at least three ways to update product labeling in response to new safety information. First, nothing in the "changes being effected" regulation, which allows manufacturers to revise labeling in advance of FDA approval in certain circumstances, distinguishes between name-brand and generic drug manufacturers. Second, no aspect of federal law explicitly forbids generic manufacturers from proposing a labeling change to FDA through the prior approval process. Finally, the court stated that generic manufacturers can suggest to FDA that "Dear Doctor" letters be sent on their behalf.

The Fifth Circuit observed that it was immaterial whether or not FDA regulations impose a duty on generic manufacturers to change their drug labels. Rather, the question is whether state law imposes duties that make compliance with federal law impossible. Rejecting preemption, the court concluded that it was avoiding the "bizarre" result of treating plaintiffs' ability to recover differently depending on whether a plaintiff took a name-brand or generic product.

AUTHORITY OF MAGISTRATE JUDGES TO IMPOSE SANCTIONS ON LAWYERS DIVIDES SECOND CIRCUIT

Finding that the record did not show that a particular allegation was "utterly lacking in support," the Second Circuit Court of Appeals has reversed an order imposing sanctions on counsel under Federal Rule of Civil Procedure 11 in an Alien Tort Claims Act case alleging violations of international law in Nigeria. [*Kiobel v. Millson*, No. 07-3903 \(2d Cir., decided January 8, 2010\)](#).

While the three-judge panel agreed that the imposition of sanctions could not stand as a matter of law because the statements counsel made did not violate Rule 11, they authored separate concurring opinions to explain whether the law allows

The issue did not need to be addressed, but the judges offered their opinions to provide guidance to other courts that may face it in the future.

federal magistrate judges to impose Rule 11 sanctions on counsel. The issue did not need to be addressed, but the judges offered their opinions to provide guidance to other courts that may face it in the future. If magistrate

judges lack this authority, they may recommend sanctions to the district court, which then considers *de novo* whether they are justified. If magistrate judges have the authority, then the district court reviews the decision with a deferential standard of review.

The key to deciding the issue that so divided the court is whether Rule 11 sanctions are dispositive or non-dispositive rulings. According to one of the concurring opinions, the issue has divided the federal circuit courts.

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FOURTH CIRCUIT DETERMINES CITIZENSHIP OF LIMITED LIABILITY COMPANY UNDER CAFA

The Fourth Circuit Court of Appeals has ruled that the Class Action Fairness Act of 2005 (CAFA), which specifies the citizenship of an “unincorporated association” for purposes of determining whether a court has jurisdiction over a matter, is applicable to limited liability companies. [*Ferrell v. Express Check Advance of SC, LLC, No. 09-2401 \(4th Cir., decided January 8, 2010\)*](#). The issue arose in a case alleging that the defendant’s “payday loans” violated state law.

The lawsuit was filed in a South Carolina state court by South Carolina residents, and the defendant removed it to federal court, alleging minimal diversity. The parties disputed the corporation’s citizenship, and the district court concluded that a limited liability company is an “unincorporated association” under CAFA. With its principal place of business in South Carolina, the defendant was thus not diverse, and the court remanded the matter to state court for lack of subject matter jurisdiction.

The appeals court agreed, rejecting the defendant’s contention that the citizenship of a limited liability company should be determined under traditional rules by looking to the citizenship of its sole member, in this case, a company organized under the laws of Kansas and Missouri.

ALL THINGS LEGISLATIVE AND REGULATORY

CPSC to Investigate Cadmium in Children’s Products

Following a press report that tests of inexpensive children’s jewelry made in China and sold in the United States revealed that some of the charm bracelets and pendants were made from cadmium, the Consumer Product Safety Commission (CPSC) announced that it has opened its own investigation and will develop mandatory standards for heavy metals in children’s products, if necessary.

Some Chinese manufacturers have apparently substituted cadmium for lead in children’s metal jewelry now that the United States has adopted stringent lead standards for consumer products.

According to CPSC Chair Inez Tanenbaum, “All of us should be committed to keeping hazardous or toxic levels of heavy metals out of surface coatings and substrates of toys and children’s products.” Some Chinese manufacturers have apparently substituted cadmium for lead in children’s metal jewelry now that the United States has adopted stringent lead standards for consumer products.

Cadmium, a known carcinogen, has also reportedly been linked to neurological problems in very young children. The Centers for Disease Control and Prevention lists cadmium as the seventh most hazardous substances in the environment on

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its priority list of 275 hazardous substances. Some of the products tested by *The Associated Press* apparently contained as much as 91 percent cadmium by weight. See *The Associated Press*, January 10, 2010; *CPSC News*, January 11, 2010.

Final Guidelines Issued on Mandatory Recall Notices

The Consumer Product Safety Commission (CPSC) has finalized a rule establishing guidelines and information to be included in mandatory consumer product recall notices. According to an agency press release, the commissioners unanimously approved the rule, which requires that recall notices include a “product description, action being taken, number of units, identification of the substantial product hazard and the reasons for the action, identification of manufacturers and significant retailers, dates when product was manufactured and sold, number and description of any injuries or deaths, the ages of anyone injured or killed, remedy available to consumer” and other appropriate information. The CPSC determined that this type of information would best improve recall effectiveness. The new rule will go into effect 30 days after publication in the *Federal Register*. See *CPSC News Release*, January 11, 2010.

Food and Drug Administration Alters Approach to Bisphenol A

The Food and Drug Administration (FDA), which previously pronounced bisphenol A (BPA), a substance found in many plastic and metal food and beverage containers, to be safe, has apparently revised its position and claims that it has “some concern”

According to FDA Commissioner Margaret Hamburg, the agency will increase its oversight of the chemical so that it will be prepared to “move quickly, if appropriate,” and adopt regulations on its use.

about the chemical’s effects on children. The agency will take a closer look at the scientific studies purportedly linking BPA to developmental and reproductive effects in exposed children. According to FDA Commissioner Margaret Hamburg, the agency will increase its oversight of the chemical so that it will be

prepared to “move quickly, if appropriate,” and adopt regulations on its use. While the FDA is not yet calling on the substance to be banned or for consumers to avoid it, parents are apparently being advised to look for alternatives, throw out worn or scratched containers and avoid exposing bottles with BPA to high heat. See *Environmental Health News*, January 15, 2010.

CRS Report Cites Federal Agencies’ Failure to Comply with Rulemaking Requirements

The Congressional Research Service (CRS) has published a report discussing the failure of federal agencies to comply with the Congressional Review Act, which has, since 1996, required that they submit their final rules to both houses of Congress and the Government Accountability Office (GAO) before they can take effect. According to the report, CRS has identified some 1,000 final rules published in the *Federal Register* during seven of the past 10 years and not submitted to GAO and/or Congress.

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The 1996 law that required agencies to submit their rules to Congress was enacted “to reestablish a measure of congressional authority over rulemaking.” It provides a mechanism for Congress to disapprove agency final rules by means of a joint resolution of disapproval and it specifically provides that “[b]efore a rule can take effect,” it shall be submitted to Congress and the GAO. According to the CRS, the law’s House and Senate sponsors issued a joint statement after it was enacted to explain that “any covered rule not submitted . . . will remain ineffective until it is submitted.” The statement also suggests that courts “might recognize that a rule has no legal effect,” if the issuing agency failed to comply with the law.

According to OMB Watch, a government watchdog group, “The revelations in the CRS report do not necessarily mean any regulation will be automatically or quickly undone. But, for better or for worse, many regulations may now be open to legal attack. If parties affected by improperly implemented regulations sue, courts could conceivably suspend regulatory requirements or fault agencies over procedure.” See *OMBWatch.org*, January 5, 2010.

LEGAL LITERATURE REVIEW

[Jane Stapleton, “The Two Explosive Proof-of-Causation Doctrines Central to Asbestos Claims,” *Brooklyn Law Review*, 2009](#)

This article discusses doctrines developed in asbestosis cases that (i) “absolve plaintiffs from the requirement of proving the portion of the total injury for which each culpable exposurer was responsible, and thereby, in effect, proceed on the fiction that asbestosis is an indivisible injury attracting joint and several liability,” and (ii) allow a plaintiff “to establish factual causation against a defendant merely by showing that the defendant’s tort exposed the plaintiff to a significant amount of asbestos and therefore to a significant risk of contracting an asbestos-related cancer,” effectively allowing plaintiffs “to proceed on the basis that each significant exposure to the risks of asbestos was causally involved in the triggering of the cancer.” The author, who teaches at laws schools in Australia and Texas, argues that these doctrines have “a truly explosive potential in the field of toxic torts beyond asbestos” and chastises the American Law Institute for failing to address them in the *Products Liability Restatement*.

[Scott Dodson, “New Pleadings, New Discovery,” *William & Mary Law School Research Paper*, January 2010](#)

William & Mary Law School Professor Scott Dodson argues that the new pleading requirements under *Iqbal* and *Twombly* should be accompanied by new discovery rules that would allow “limited presuit or pre-dismissal discovery to provide plaintiffs the opportunity to gather the facts necessary to comply with New Pleading’s strictures.” According to Dodson, plaintiffs may plead their cases with insufficient facts, not because their cases lack merit, but because the information they need

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is controlled by the defendant. He outlines ways to strictly limit such discovery to balance information asymmetry with discovery costs: (i) use it sparingly, (ii) focus it narrowly to minimize undue costs, and (iii) toll the running of any applicable limitations period.

LAW BLOG ROUNDUP

The Role of the Judge in Decisionmaking

...“every now and then a decision appears so nakedly political as to shake the faith of us post-realists, leaving us wondering whether a different sort of radical legal realist view is right—what I shall call ‘legal surrealism.’” Cornell Law Professor Mike Dorf discussing legal realism, which posits that “judges make decisions based on their values, ideologies and backgrounds,” and pondering the meaning of the U.S. Supreme Court’s 5-4 decision prohibiting the video broadcast of proceedings in a challenge to California’s ban on same-sex marriage. Dorf was struck by the split between the Court’s conservative and liberal members on an issue—“whether to allow cameras in the courtroom”—that seems devoid of political ideology.

Dorf on Law, January 19, 2010.

THE FINAL WORD

[Mark Behrens and Cary Silverman, “Alabama Supreme Court Rejects Pharmaceutical Pricing ‘Regulation Through Litigation,’” *Washington Legal Foundation Legal Opinion Letter*, January 15, 2010](#)

Shook, Hardy & Bacon Public Policy attorneys [Mark Behrens](#) and [Cary Silverman](#) discuss the Alabama Supreme Court’s decision to reverse verdicts against three prescription drug makers totaling more than a quarter billion dollars. At issue was the price for drugs covered under state Medicaid programs. According to the article, many states represented by contingency fee lawyers have sued most major drug makers, alleging fraud in the reporting of prices for drugs covered under these programs. The states claim they were unaware that manufacturers’ “list prices” for drugs, which are reimbursed by the states, do not include discounts, rebates or other price concessions. They contend that pharmaceutical providers were over-reimbursed because the states used the reported list prices in their Medicaid reimbursement formulas. Behrens and Silverman call such litigation “faux legislation” and suggest that the court’s opinion, which found the state’s purported reliance untenable, represents a significant hurdle for states in related cases.

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UPCOMING CONFERENCES AND SEMINARS

HB Litigation Conference, Marina del Rey, California – March 3-5, 2010 – “3rd Annual Emerging Trends in Asbestos Litigation Conference.” Shook, Hardy & Bacon Public Policy Partner **Mark Behrens** will participate in a panel to discuss “The Role of the Bankruptcy Trusts in Civil Asbestos.”

GMA, Washington, D.C. – April 7-9, 2010 – “Consumer Complaints Conference.” Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Madeleine McDonough** will discuss “Pre-Litigation Risk Management Strategies,” for an audience of food industry staff working in the areas of consumer affairs, call center management, consumer complaints, product liability claims, and quality assurance. ■

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