ReedSmith

Fall 2007
Volume XI, Number 3

HEALTH LAW Monitor

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Supreme Court to Rule on Federal Preemption Cases Regarding State Regulation of Pharmaceutical and Medical Device Products

By Frederick H. Branding and Celeste A. Letourneau

Two product liability cases on the Supreme Court's docket have set the stage for the Court to rule on the issue of preemption of state efforts to regulate pharmaceutical and medical device products. It long has been FDA's position that FDA approval of labeling under the Federal Food, Drug, and Cosmetic Act preempts conflicting or contrary state law. FDA, in court filings, has made it clear that decisions by state and federal courts, imposing liability on manufacturers under state tort law theories, conflict with FDA's statutory authority, regulations, and public health mission. *Warner-Lambert v. Kent* arises in the context of a conflict among circuit court decisions with regard to the application of federal preemption of state law exceptions for fraud-on-the-FDA involving an approved pharmaceutical product. *Riegel v. Medtronic* revisits the question of whether a specific provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state law claims for injuries caused by medical devices that received premarket approval ("PMA") from FDA. This article first discusses the two Supreme Court cases and then comments on the potential implications of the Court's decisions.

Warner-Lambert v. Kent *(467 F.3d 85 (2d Cir. 2006), U.S. No. 06-1498)*

Respondents in *Warner-Lambert v. Kent* are Michigan citizens who brought suits claiming injuries resulting from taking Rezulin, a prescription drug used to treat Type-2 diabetes. Asserting various common law claims, including defective design and fraud, the respondents alleged Warner-Lambert "knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal." For jurisdictional reasons, the cases were removed to the Judicial Panel on Multidistrict Litigation in the Southern District of New York.

Warner-Lambert argued liability was foreclosed under a Michigan law that shields FDA-approved drugs from liability based on defective design. Warner-Lambert

(continued on page 14)

In the Spotlight: Food and Drug Law

The cover story in this issue of *Health Law Monitor* discusses two upcoming Supreme Court cases that will affect regulation of pharmaceutical and medical device products. Reed Smith's FDA Counseling & Litigation Team, along with the International Regulatory Group, has developed an integrated and holistic approach to help clients maintain regulatory compliance while marketing pharmaceuticals, medical devices, biological products, human cells, tissues, cellular and tissue-based products, foods, dietary supplements, and cosmetics, with confidence. Our best strategy for success to ensure regulatory compliance with FDA—from clinical trials to the submission of marketing applications to post approval (or clearance) compliance—is threefold: Risk Assessment, Risk Management, and Crisis Management. We provide comprehensive risk assessments to identify problems before they occur; in-depth risk management counseling to address problems and questions as they occur; and unparalleled support in times of crisis. We understand the broad spectrum of risks presented by FDA enforcement actions, health care regulatory and legislative mandates, fraud and abuse rules and OIG compliance, Securities and Exchange Commission filings, Compliance with the Drug Enforcement Administration ("DEA") and the U.S. Department of Agriculture ("USDA"), and import and export enforcement. Regulatory attorneys in our European offices help us provide unparalleled and seamless international support in connection with all of these areas for our global clients.

Our ongoing work in product development and marketing gives us an edge in addressing a crisis or potential crisis. With decades of experience at, and with, the FDA, we can navigate agency inquiries and chart a course to resolution that protects product investments from becoming mere sunk costs. Our FDA Team, which includes not only two former FDA Associate Chief Counsels, but also former Assistant U.S. Attorneys in both criminal and civil matters, provides a wealth of experience in preventing, mitigating, and defending against government enforcement actions. Our FDA Team is a coalition of attorneys with the relevant knowledge and skills to help companies make good decisions in line with strategic and business operational goals.

Our Reed Smith team also helps clients establish and foster good relationships with key regulatory contacts at the FDA, state agencies, and other government authorities in the United States and abroad. Our European and Middle East Life Sciences Team is made up of regulatory, IP, and transactional lawyers and litigators, including ones from our Hong Kong office. Our Team includes lawyers who are pharmacists and economists, and authors on many important topics. Our international experience is vast. From risk assessment to real-time counseling and crisis support, we work to become more than legal counsel. The goal of Reed Smith's FDA Team is to provide insightful counseling and representation, and to provide support throughout product development, launch, and marketing.

Reed Smith also has a Food Team of compromised food industry attorneys, including former government attorneys, who counsel and represent clients in all sectors of the food industry, such as major food and dietary supplement companies, food packaging companies, restaurants, alcoholic beverage manufacturers, and agricultural producers. With our in-depth knowledge of the industry and the many regulatory issues that affect it, we are able to provide value-added and responsive counsel. Our integrated approach to client service allows us to tailor our services to each food client's strategic business goals and challenges, including corporate transactions; risk mitigation; regulatory counseling; advertising, technology and media; government contracts, import-export; lobbying; labor and employment; intellectual property; recall strategies; and complex litigation and class action defense.

Avoiding Liability for Negligent Credentialing

By Robert K. Neiman

Hospitals and other providers that adopt—but then fail to follow—their own staff credentialing standards can incur liability under a "negligent credentialing" theory recently adopted by an Illinois appellate court. Providers that follow their credentialing standards when appointing a doctor to their staff do not incur such liability, even if the doctor then commits malpractice, the court held.

The lesson from this Illinois "negligent credentialing" case, *Frigo v. Silver Cross Hosp.*, No. 1-05-1240, 2007 WL 2736595 (Ill. App. Ct. Sept. 20, 2007), and similar cases in other states is simple: providers must exercise care and strictly follow their credentialing procedures when considering whether to appoint a doctor to their staff to avoid incurring unnecessary liability.

In the Illinois case, a hospital granted category II surgical credentials to a doctor. A patient sued both the hospital and the doctor for damages resulting from foot surgery performed by the doctor at the hospital, alleging that the doctor committed malpractice by performing elective bunion surgery before an ulcer on the foot had fully healed. The doctor's malpractice allegedly resulted in the amputation of the patient's foot. The patient sued the hospital for negligent credentialing, alleging that the hospital granted the doctor category II surgical privileges even though he did not meet the hospital's requirements for such privileges.

The plaintiff alleged that the hospital ignored its credentialing procedures because the doctor had not completed a 12-month podiatric surgical residency and was not board-certified as the hospital's bylaws and JCAHCO standards required.

The jury awarded the patient $7,775,668.02 in damages against the hospital. The hospital appealed, contending that Illinois law does not recognize negligent credentialing claims.

The hospital first argued that its credentialing process constituted privileged peer review information under a state statute that prohibits a plaintiff from seeking discovery of such peer review documents as proof of negligence. The court, however, ruled that the statute protects against disclosure of peer-review process mechanisms, such as investigations and deliberations leading to peer-review committee decisions about a doctor's performance. The statute does not, according to the court, prohibit discovery of information before the peer-review process begins, such as whether the hospital followed its own guidelines in granting staff privileges to a doctor. The court therefore held that the plaintiff was entitled to discover and use facts about the hospital's negligence in following its credentialing standards.

The hospital also argued that the Illinois Hospital Licensing Act immunized it from negligent credentialing liability. That statute says that hospitals have no liability for the acts, omissions, or decisions of any committee or person directly or indirectly responsible for staff privilege decisions or disciplinary actions against doctors.

The court, however, ruled that the statute immunizes hospitals from liability against doctors who disagree with a hospital's staff privilege and disciplinary decisions, but not liability resulting from the hospital's negligent failure to follow its credentialing standards.

The court cited a growing trend in other states recognizing negligent credentialing claims and other theories detailing a hospital's institutional duty to its patients. In recognizing the tort of negligent credentialing, the court said that a plaintiff must prove that:

- The hospital failed to use reasonable care in granting staff privileges to a doctor whose treatment injured the plaintiff;
- The doctor, while practicing pursuant to negligently granted staff privileges, breached the applicable standard of care; and
- The hospital's negligent granting of staff privileges proximately caused the plaintiff's injuries.

In reviewing the evidence at trial, the court found that the plaintiff met all of these criteria. The hospital's credentialing criteria required a category II surgeon to have completed a surgical residency and become board certified. The doctor in question did not meet these or other criteria. The court also found enough evidence that the hospital's failure to follow its criteria proximately caused the plaintiff's injuries.

Providers should take at least some comfort in the court's distinction between negligent credentialing and medical malpractice. Just because a staff doctor commits malpractice does not make the hospital liable for negligently granting privileges to that doctor. Rather, a hospital only becomes liable for negligent credentialing if its failure to follow its own credentialing standards proximately caused a patient's injury.

Exclusive Contracting: Proceed with Caution

By Cynthia A. Alcantara

Competition among providers both for exclusive contracts and for exceptions to exclusivity has grown increasingly commonplace. Although exclusive contracts continue to survive legal attacks, courts also continue to scrutinize such contracts in light of new legal theories. Two recent federal appeals court opinions evidence the continuing trend of courts upholding exclusive contracts between hospitals and hospital-based physicians, such as radiologists, anesthesiologists and emergency room physicians. Although a growing line of case law in various jurisdictions grants wide deference to hospitals to administer their departments and deny or terminate medical staff privileges to practice in closed departments, physicians continue to challenge exclusive contracts under novel legal theories, most often under antitrust laws, breach of implied contract or due process rights. The facts, reasoning and considerations may vary by case, but courts generally recognize a hospital's ability to exclude hospital-based physicians from exercising privileges when a hospital enters into an exclusive contract with another hospital-based physician group.

> "Physicians continue to challenge exclusive contracts under novel legal theories."

The U.S. Court of Appeals for the Tenth Circuit denied a radiologist, Robert Stears, M.D., the right to pursue due process and breach of contract claims against a Wyoming hospital that denied the radiologist the right to exercise privileges after it entered into an exclusive contract with another radiology group. *See Stears v. Sheridan County Memorial Hospital Board of Trustees*, 491 F.3d 1160 (10th Cir. 2007). Dr. Stears had previously been the exclusive provider of radiology services at the hospital, but terminated his contract with the hospital after failed attempts to renegotiate the non-competition provision of the agreement. Dr. Stears continued to provide radiology services at the hospital for a few months after the contract terminated. The hospital then entered into an exclusive agreement with another radiology group and notified Dr. Stears that the radiology department would be closed to radiologists who were not affiliated with the new exclusive provider. Although Dr. Stears technically retained active medical staff membership, including the right to vote, hold office and serve on medical staff committees, he was excluded from exercising his privileges at the hospital without any rights to a hearing under the medical staff bylaws. He argued that he was being denied due process rights under federal law, as well as rights under a Wyoming anti-discrimination law and the hospital's bylaws.

The court held that Dr. Stears could not pursue due process claims because, since his clinical privileges were never terminated, he was not deprived of a property interest. In fact, if Dr. Stears joined the radiology group with exclusive rights to provide radiology services, he could exercise his privileges to provide radiology services at the hospital. A number of other courts recognize the distinction between having medical staff privileges and being able to exercise those privileges. The Tenth Circuit reasoned that even if the property interest was not in the privileges themselves, but in the right to exercise them, Dr. Stears did not have a legitimate claim of entitlement to this interest. It also emphasized that the grant of privileges did not constitute any contractual rights. The court found that since Dr. Stears' privileges were restricted only as a result

of the exclusive contract with another group, and not as a measure related to professional performance, he was not entitled to procedural rights. The appeals court ruling affirmed a trial court decision that Dr. Stears could not demonstrate the deprivation of a vested liberty or property interest, and could not show that his contract rights were violated by the hospital's business decisions.

Similarly, the Sixth Circuit Court of Appeals found no violation of antitrust laws by a two-hospital health system in Ohio entering into an exclusive radiology services contract. *See Nilavar v. Mercy Health System-Western Ohio*, No. 06-3819, *unpublished* (6th Cir. 2007). Dr. Nilavar's antitrust theory was that the hospital system excluded other radiology providers by granting an exclusive contract for radiology services to a group that complied with the hospital's cost reduction goals by using more temporary and part-time physicians, and also by using less expensive agents in radiology procedures, which resulted in higher prices and lower quality radiology services at the system's two hospitals. There was no evidence of patient harm. At the trial court level, plaintiff Sundar Nilavar, M.D.'s other claims were dismissed, including an argument that the hospital deprived him of due process and breached medical staff bylaws when he was denied a hearing prior to the termination of his privileges after the hospital signed the new contract with another provider. No notice or hearing was required, according to the trial court, because the hospital's decision to enter into an exclusive contract for medical services related solely to the hospital management and administrative matters, and was unrelated to Dr. Nilavar's professional competence.

Although the court ultimately found no antitrust violation, several factors considered by the court are notable. One factor was that the hospital solicited several competing radiology groups, of which seven responded to a request for proposal for an exclusive contract. According to the court, the exclusive contract was a result of competition and not a limitation. The court also found that the loss of staff privileges of several former radiologists after the new exclusive contract did not result in a decrease in radiology services. The short two-year term of the exclusive contract was also addressed. The court characterized this case as essentially involving a hospital's staffing decision and choice of provider of services. Relying on extensive court precedent upholding exclusive contracts under antitrust laws, the court found that the hospital system's decision regarding staffing and privileges was not anticompetitive.

Many courts continue to recognize the validity of exclusive hospital-based contracts and to allow deference to hospitals to administer their bylaws and deny, limit or terminate medical staff privileges. In the landmark case, *Jefferson Parish Hospital District No. 2 v. Hyde*, 466 U.S. 2 (1984), the United States Supreme Court upheld an exclusive contract between a hospital-based group and a hospital, and held that other individual physicians may be denied staff privileges. Since that decision in the mid-1980s, many hospitals and hospital-based physicians groups have chosen to enter into exclusive contracts. Also since that time, many courts have dismissed legal challenges to exclusive contracts as violating due process or antitrust laws. Justifications for exclusive contracts include enhancing the quality of care and increasing the efficiency of the hospital and the department. As a result, despite advancing new and creative arguments, physicians such as Dr. Stears and Dr. Nilavar have generally been unsuccessful in obtaining relief from termination or limitations of privileges as a result of exclusive contracts.

As exclusive contracts become more nuanced, different factual issues may emerge, and scrutiny will increase. These future challenges may prove more successful. For example, a hospital may have difficulty defending an exclusive radiology contract when numerous non-radiologist physicians have been granted privileges to perform imaging services despite the exclusive contract. Until then, however, it appears that the courts remain supportive of hospitals' exclusive contracting and privileging actions.

Medicare Moves Forward with Hospital Quality Initiatives and Value-Based Purchasing

By Gail L. Daubert, Robert J. Kaufman, and Alison F. MacManus

> "CMS intends to become an 'active purchaser' of health care, thereby driving increased quality and efficiency in health care delivery."

The Centers for Medicare & Medicaid Services ("CMS") intends to become an "active purchaser" of health care, thereby driving increased quality and efficiency in health care delivery. In 2009, the various elements of CMS' Hospital Quality Initiative ("HQI") will converge into a comprehensive Value-Based Purchasing ("VBP") plan, which the agency believes will transform the way that Medicare pays for health care. Value-Based Purchasing will be both a pay-for-performance system and a public information and comparison tool. In this article we first examine the component pieces of the current HQI, and then discuss CMS' proposed plan to build on and—in some cases—transform each piece into the unified VBP plan. Clients with technologies that link to better patient outcomes or quality measurements may wish to highlight these developments when speaking with health care providers, and look for ways to work with CMS to develop additional quality measures that include their technology.

Reporting of Hospital Quality Data Linked to Annual Payment Update

The Hospital Quality Data ("HQD") initiative was initially developed as a result of the Medicare Prescription Drug Improvement and Modernization Act ("MMA") of 2003. The Deficit Reduction Act ("DRA") of 2005, in turn, set out new requirements for the HQD program, increasing both the number of quality measures on which hospitals must report data and the amount of the penalty reduction in the Annual Payment Update ("APU") for non-reporting hospitals. As of 2007, hospitals paid under Medicare's inpatient prospective payment system ("IPPS") who do not submit data on 21 measures will receive a 2 percent reduction in their APU.

The HQD measures are clinical, evidence-based "process of care" measures. Among the conditions covered by the current 21 measures are acute myocardial infarction, heart failure and pneumonia. Also addressed is the broader category of surgical care improvement. Specific measures include "patient given aspirin at arrival" for heart attacks and "patient given oxygenation assessment" for pneumonia.

Consumer Assessment of Health Providers and Systems Survey for Hospitals

Beginning in FY 2008, IPPS hospitals also must meet reporting requirements for this new standardized survey of consumers to receive the full annual payment update. The survey is designed to create information for policy-makers and stakeholders, as well as consumers themselves, regarding hospital performance. As such, it fills a gap in national information available, enabling "apples to apples" comparison across certain measures for various hospitals.

The Consumer Assessment of Health Providers and Systems Survey for Hospitals ("HCAHPS") is composed of 27 items: 18 substantive items that encompass critical aspects of the hospital experience (communication with doctors and with nurses, responsiveness of hospital staff, cleanliness and quietness of the hospital, pain control, communication about medicines, and discharge information); four technical items to facilitate reporting; three items to adjust for the mix of patients across hospitals; and two items to support congressionally mandated reports. This initiative is currently in the "dry run" stage, with initial publication planned for March 2008.

Premier Hospital Quality Incentive Demonstration

This demonstration is a trial run of the pay-for-performance model. Under this program, CMS rewards top-performing hospitals in five clinical areas: acute myocardial infarction ("AMI"), heart failure, community-acquired pneumonia, coronary artery bypass graft ("CABG"), and hip and knee surgery. Any hospital subscribing to Premier's *Perspectives* database can participate, because this system was already set up to track and report data on 30 quality measures, enabling a very quick evaluation of the success of the use of incentives to increase quality performance.

CMS has stated that it is pleased with the results. In the first year of the demonstration, composite quality scores for each measure rose between 4 and 14 percent. The overall improvement after the second year of the demonstration was estimated at 11.8 percent. CMS' former Acting Administrator, Leslie Norwalk, cites these improvements as evidence that even limited additional payments can drive "across-the-board improvements in quality, fewer complications, and reduced costs." The incentive structure used for the demonstration was a 2 percent bonus on Medicare payments for a given condition for hospitals in the top 10 percent, a 1 perecent increase for those in the second 10 percent, and recognition for the remaining top half of hospitals. Meanwhile, those hospitals that fail to improve beyond a baseline defined by the lowest 20 percent of hospitals at the end of the first year face reduction from the third year forward.

Lessons learned from this pay-for-performance demonstration, along with the infrastructure of the HQD pay-for-reporting system, will be used to structure the Value-Based Purchasing plan described below.

Future Plans: Options for VBP

Value-Based Purchasing is the unified quality program that CMS' other quality initiatives will eventually combine to produce. As described by a CMS Options Paper released in April of this year, VBP will encompass both public reporting and financial incentives for high performance in order to drive improvements in clinical quality, patient-centeredness and efficiency. Like the HQD program, the broad approach was mandated by the DRA of 2005. VBP commences October 2008, and CMS has been engaged in a series of listening sessions with stakeholders to craft program specifics.

VBP is designed to reward both attainment and improvement. CMS further asserts that the program has been designed to "raise all boats" rather than separate out winners and losers. Once fully implemented, CMS will produce an overall performance score for each provider using methodology called the Performance Assessment Model. Under this model, hospitals will receive 0 to 10 points for each measure, based either on improvement or on attainment of a benchmark number of patients given the required care. These scores combine to produce an overall performance score which CMS will translate into the incentive payment using an "exchange function." Fifteen measures from HQD program will form the initial set of measures, and CMS will add new measures and change existing ones as the program progresses. Future measures will likely include measures relating to patient safety, efficiency, care coordination, and emergency care.

Editors' Note: Ms. MacManus was a 2007 summer associate with Reed Smith.

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Deborah Bey · Reed Smith LLP
Phone: 412.288.3223 · Fax: 412.288.3063 · *dbey@reedsmith.com*

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Washington Corner

An update on the latest legislative and regulatory developments affecting the health care industry

Regulatory News

On Nov. 1, 2007, the Centers for Medicare & Medicaid Services ("CMS") released its final Medicare physician fee schedule rule for calendar year ("CY") 2008. The rule calls for a 10.1 percent across-the-board cut in physician payments because of the statutory update formula, although Congress is expected to take action to avert or mitigate the cuts later this year. The rule also includes a number of major revisions to the independent diagnostic testing facility performance standards and purchased diagnostic test rule that have the potential to significantly impact certain types of physician-owned imaging ventures (a Reed Smith memorandum analyzing these provisions is available on our website). This sweeping rule also features other important policy provisions, including among many other things: implementation of the Physician Assistance and Quality Initiative Fund (which will provide $1.35 billion for physician payment and quality improvement initiatives for services furnished in 2008); updated personnel qualifications for persons furnishing physical and occupational therapy services; and revisions to the public consultation procedures for new clinical diagnostic laboratory test payment.

Also on Nov. 1, CMS released its final Medicare hospital outpatient prospective payment system ("OPPS") rule for CY 2008. CMS estimates that the rule will provide a 3.8 percent average increase in Medicare payments for outpatient services. In addition to updating payment amounts, the final rule institutes a number of policy changes, including the following:

- *Packaging* – CMS is expanding the current "packaging" policy to bundle payment for seven categories of supportive ancillary services into the primary diagnostic and treatment procedures with which they are performed.
- *Composite APCs* – CMS has adopted "composite ambulatory payment classifications" ("APCs"), through which a single payment will be made for multiple major procedures performed in a single hospital encounter.
- *Quality Reporting* – The rule requires hospitals that are paid under the Medicare inpatient prospective payment system ("IPPS") to report on seven outpatient quality measures for services furnished in the hospital outpatient department in 2008 in order to receive the full OPPS market basket update in CY 2009; otherwise, the update will be reduced by 2 percentage points.
- *Payment for Drugs* – The rule provides separate payment for drugs, biologicals, and therapeutic radiopharmaceuticals costing more than $60 or more per day (up from $55 in 2007); generally sets payment for nonpass-through separately payable drugs and biologicals at ASP plus 5 percent (instead of the current ASP plus 6 percent); and reimburses drugs and biologicals with pass-through status at ASP plus 6 percent.
- *Replacement Devices* – The rule reduces payment for certain device-dependent APCs when a hospital receives a partial credit from the manufacturer toward the cost of a replacement device implanted in a procedure.

- *Graduate Medical Education ("GME")* – The rule extends the effective period for emergency Medicare GME affiliations from three academic years to up to five academic years in general (with certain limitations for out-of-state emergency affiliations), and adopts other revisions to GME policy.
- *Ambulatory Surgical Center ("ASC") Policy* – The final rule also updates relative payment weights and amounts for services furnished in ASCs, specific codes to which the final policies of the ASC payment system apply, and other pertinent rate setting information for the revised ASC payment system for 2008.

On Sept. 5, 2007, CMS published its major "Stark III" Medicare physician self-referral final rule. While the new rule does not establish new exceptions to the self-referral prohibition, CMS asserts that the rule reduces the regulatory burden on the health care industry through its refined interpretation of the current exceptions, which will permit (and in some cases will require) restructuring of existing arrangements. The rule is effective Dec. 4, 2007. A Reed Smith client memorandum summarizing the rule is available on our website. Note that on Nov. 15, CMS published a notice delaying for one year certain limited provisions of the rule.

On Oct. 5, 2007, the Office of Inspector General of the Department of Health and Human Services issued a final rule establishing a safe harbor under the anti-kickback statute to protect certain arrangements involving remuneration in the form of goods, items, services, donations, or loans furnished by a provider or supplier to certain federally qualified health centers. The rule is effective Dec. 3, 2007.

Other recent regulations include the following:

- A CMS proposed rule narrowing the definition of Medicaid outpatient hospital services to modify how upper payment limits are applied, provide more transparency in determining available coverage in any state, and clarify the services for which federal financial participation is available (Sept. 28)
- A CMS notice regarding proposed hospital reporting requirements regarding investment, ownership, and compensation arrangements between physicians and hospitals (Sept. 14)
- A CMS proposed rule amending the Medicare conditions for coverage for ambulatory surgical centers (Aug. 31)
- The final 2008 Medicare home health prospective payment system rule (Aug. 29)
- An interim final rule with comment period establishing new Medicare conditions of participation requirements for hospitals that transfuse blood and blood components (Aug. 24)

Legislative News

On Sept. 27, 2007, President Bush signed into law H.R. 3580, the Food and Drug Administration ("FDA") Amendments Act of 2007 ("FDAAA"). This is the most significant revision of FDA's safety authority since 1962, particularly in the area of post-approval surveillance of safety information. The new law permits FDA to require (1) post approval studies and clinical trials; (2) risk evaluation and mitigation strategies for certain products; and (3) pre-review of direct-to-consumer ("DTC") advertisements. FDAAA also authorizes FDA to level considerable civil money penalties against manufacturers that violate the DTC and drug safety provisions. Reed Smith has prepared an analysis of the new law, which is available on our website.

There has been a great deal of attention in Washington regarding reauthorization of the State Children's Health Insurance Program ("SCHIP"). On Oct. 18, 2007, the House of Representatives failed to override President Bush's veto of H.R. 976, a $35 billion package that would have reauthorized and expanded SCHIP. The House and Senate subsequently approved another version of legislation (H.R. 3963), again with insufficient support to override an expected veto.

In addition, on Sept. 29, 2007, President Bush signed into law H.R. 3668, which extends the Transitional Medical Assistance, Abstinence Education, and Qualifying Individuals programs, and modifies certain Medicare and Medicaid programs. Among other things, the legislation cuts in half the "behavioral offset" reduction included in the final FY 2008 Medicare hospital inpatient prospective payment system rule; provides additional funding for the Medicare physician assistance and quality initiative fund; and delays for six months (until April 1, 2008) the requirement for Medicaid programs to use tamper-resistant prescription pads.

For a biweekly update on legislative, regulatory, and other federal policy developments affecting the health care industry, sign up for "Reed Smith Health Industry Washington Watch" by contacting Debbie McCurdy at dmccurdy@reedsmith.com.

Health Law 101: Medicare Coverage and Payment Basics

In this section of the Health Law Monitor, *we will examine a basic principle of the health care law in greater depth.*

By Catherine A. Durkin and Kevin M. Madagan

Medicare is a federally funded social health insurance program that consists of four "parts" or types of benefits—A, B, C, and D—each covering different items, services, or types of care, and paid for pursuant to specific payment methodologies. The following is a brief overview of what services and items Medicare generally covers under the various benefits, and a summary of Medicare's primary payment systems for Parts A and B.

> "Part B is a supplementary insurance benefit that is generally similar to private health insurance in that it requires beneficiaries to pay a monthly premium, satisfy a deductible, and pay co-insurance."

What Health Care Items and Services Are Covered by Medicare?

Part A – Hospital Insurance

Medicare Part A covers hospital inpatient services, post-hospital skilled nursing facility ("SNF") care, certain home-health services, and hospice care.

With respect to hospital inpatient services, Part A generally covers the costs associated with a hospital stay, whether it be in a general acute care hospital or a specialty hospital (such as a long-term acute care hospital, psychiatric hospital, or rehabilitation hospital), up to 90 days per "spell of illness."

After 90 days, if the beneficiary is not well enough to return to his or her normal routine, Part A covers other types of care. If the beneficiary is still extremely ill, Part A covers the cost of staying in a skilled nursing facility or SNF for up to 100 days per spell of illness. However, the SNF benefit is only available where the beneficiary is admitted to the SNF within 30 days of being discharged from the hospital. If the beneficiary is well enough to return home but ill enough that he or she will be confined to the home, Part A covers up to 100 home health visits. The home health benefit is only available where the beneficiary required a hospital or SNF stay of three days or longer, and was discharged from that stay within 14 days of the first home health visit. If the beneficiary is terminally ill and elects hospice coverage, Part A covers pain management, palliative care, and other associated services and supplies, including drugs, provided in a variety of settings (for example home, hospital, or SNF) for 90-day or 60-day benefit periods.

Part B – Supplementary Insurance

Part B is a supplementary insurance benefit that is generally similar to private health insurance in that it requires beneficiaries to pay a monthly premium, satisfy a deductible, and pay co-insurance. If beneficiaries elect Part B coverage, it covers a variety of health care services and items, subject to certain exclusions and limitations. Examples include office visits (such as a physician's professional services plus those services performed in the physician's office that are "incident to" the physician's services), outpatient hospital department care, diagnostic laboratory services, physical/occupational therapy, and some home health care. It also covers items to be used in the home that meet the Medicare definition of durable medical equipment ("DME") (for example, wheelchairs, walkers, and inhalers), prosthetic devices (such as artificial limbs, pacemakers, etc.), items furnished to beneficiaries "incident to" the physician's services (such as splints, casts, etc.), and certain drugs that either meet specific criteria with respect to

how they are administered or are expressly authorized by the Social Security Act.

Part C – Medicare Advantage

Part C is otherwise known as the Medicare Advantage ("MA") program (formerly, Medicare + Choice). Through Part C, Medicare beneficiaries who are entitled to Part A benefits and are enrolled in Part B can choose to receive health benefits from private health plans offered by MA organizations. Three different types of plans are available under Part C: coordinated care plans (for example, health maintenance organizations—"HMOs"; provider-sponsored organizations—"PSOs"; special needs plans—"SNPs"; and preferred provider organizations—"PPOs"), private fee-for-service plans, or combination plans (which include both a basic health plan and a medical savings account into which CMS will make deposits).

At a minimum, MA plans must cover "basic benefits"—*i.e.*, those services that are otherwise covered under Medicare Parts A and B (discussed above), except for Part A hospice services. MA plans also may offer optional supplemental benefits at an additional cost to beneficiaries, as long as the option is available to all beneficiaries in the plan, or requires beneficiaries to purchase supplemental benefits, subject to CMS approval.

Part D – Prescription Drug Benefit

Medicare Part D is the Medicare prescription drug benefit that became effective Jan. 1, 2006 and covers outpatient prescription drugs. Through contracts with CMS, plan sponsors offer coverage through various types of plans (for example, stand-alone prescription drug plans—"PDPs," or Medicare Advantage prescription drug plans—"MA-PDs"). Whether specific types of drugs are covered depends on the individual plan's formulary and, in some cases, the setting where the drug is being administered. CMS requires each plan's formulary to include at least two drugs from each therapeutic category. If specific drugs are not on a plan's formulary, they are generally not covered unless the drug is medically necessary, in which case the beneficiary may be entitled to an exception. Further, if drugs are covered under Parts A or B, Part D coverage is not available.

In addition, coverage is only available up to a certain threshold, above which there is a coverage gap (known as the "donut hole") until a beneficiary's drug expenditures reach the "catastrophic" threshold when coverage is once again available. The beneficiary is responsible for the cost of all outpatient prescription drugs unless/until out-of-pocket expenditures exceed the coverage-gap limit.

What Are the Payment Systems for Medicare Parts A and B?

Complex payment systems reimburse providers and suppliers under Parts A and B. The most prevalent systems are Prospective Payment Systems ("PPS") and fee schedules. The following is a brief overview of these payment systems.

Prospective Payment System

Established to create an incentive for health care entities to operate more efficiently and more profitably, the Medicare PPS identifies pre-determined prices that Medicare uses to reimburse many health care providers and suppliers for services provided to beneficiaries. Theoretically, beneficiaries receive better, more focused treatment under a PPS methodology than a traditional fee-for-service reimbursement system.

A traditional fee-for-service system ties a health care provider's revenue stream directly to the number of procedures performed for a beneficiary (*e.g.*, each exam, each test, and each procedure). Under the Medicare PPS, health care entities are paid one predetermined flat rate for care that is based on the beneficiary's diagnosis and condition. Because a health care entity receives only a preset PPS amount—regardless of actual costs incurred—a PPS payment may exceed a provider's full costs for treating the beneficiary, thereby forcing the facility to absorb the excess cost. By changing the revenue stream, the PPS system's reimbursement methodology places inherent pressure on providers and suppliers to streamline their operational costs and treatment—such as eliminating redundant or unnecessary tests on patients whose medical problems are straightforward.

Largely following the hospital PPS model, PPS methodologies have since been developed for each of the other major parts of Part A coverage—inpatient rehabilitation, long-term care hospitals, skilled nursing facilities, home health agencies, and inpatient psychiatric facilities.

Prospective Payment System Methodology – In general, a PPS rate represents the average cost, nationwide, of treating a Medicare beneficiary according to his or her medical condition, or the average cost of providing certain outpatient services. Medicare employs two complex classification systems to identify these average costs—diagnostic related groups ("DRG") for inpatient services, and am-

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bulatory payment classification ("APC") groups for outpatient services.

Diagnostic Related Groups – DRG classifications are used in the inpatient prospective payment system ("IPPS") for inpatient hospital stays. Medicare sets prices for more than 550 DRGs that are organized into 25 major categories. Only one DRG is assigned to a patient for a particular hospital admission. The scope of each DRG encompasses a principal diagnosis and procedure, which has a payment weight assigned to it, based on the average resources used to treat a Medicare beneficiary in that DRG. Secondary diagnosis, beneficiary age, sex, discharge status, and the presence or absence of complications and comorbidities also factor into DRG payment weights and assignments. The location and type of hospital may impact DRG payments as well. For example, a hospital-wide percentage add-on payment is applied to the IPPS payment rate for teaching hospitals and hospitals that treat a high percentage of low-income patients.

> "DRG classifications are used in the inpatient prospective payment system for inpatient hospital stays."

While only one DRG payment covers all hospital costs for treating a beneficiary during a specific inpatient stay, a Medicare safety net applies to unusually costly inpatient hospital cases. These Medicare "outlier" payments are additional payments designed to protect a hospital from large financial losses as a result of unusually expensive cases.

Ambulatory Payment Classification Groups – Serving in the same capacity as DRGs in the inpatient payment system, APC groups are predetermined payment rates employed by the outpatient prospective payment system ("OPPS") for designated services furnished by hospitals and other facilities providing outpatient services. Each APC group contains services and procedures that are clinically comparable and use roughly the same amount of resources. Currently, more than 450 APC groups cover services such as surgical procedures, radiology and other diagnostic procedures, clinic visits, emergency department visits, medical supplies and surgical dressings, and various preventive services.

However, unlike DRGs under the inpatient payment system, depending on the number and type of outpatient services provided to a beneficiary, single or multiple APC groups, each with separate associated reimbursement payments, may apply.

Fee Schedules

Medicare Part B currently employs complex fee schedules to reimburse physicians and other health care suppliers of services and equipment.

Part B services provided by physicians and other health care suppliers are reimbursed through the "physicians' fee schedule." This fee schedule is an elaborate price list that Medicare uses to reimburse physicians for the services they, and other health care suppliers, furnish for items and services that are not "bundled" into PPS methodologies—things like clinical laboratory tests, durable medical equipment, and some prosthetic devices. For each service provided, there is an associated reimbursement rate that Medicare recalculates annually.

Other suppliers of services and equipment (*e.g.*, durable medical equipment, prosthetic devices, and orthotics) are reimbursed under Part B through either regional fee schedules or on a "reasonable charge" basis. However, as a result of the Medicare Prescription Drug Improvement and Modernization Act of

2003 ("MMA"), Medicare will shift from a fee schedule to a competitive bidding system. Payments will soon be based on competitive bids in which CMS will determine a single payment amount for each item or service in separate competitive acquisition areas. By 2009, competitive bidding will occur in 80 of the nation's largest metropolitan statistical areas. The remaining areas will have competitive bidding phased in after 2009.

In the News

Lorin E. Patterson wrote an article entitled "Managing Relations in Physician-Owned ASC Partnerships," which appeared in September in *Today's Surgicenter.*

"Partner with Hospitals, But Approach Carefully," an article by **Thomas W. Greeson**, was published in the September edition of *Diagnostic Imaging*. In addition, Tom's article entitled "Medicare Rules for Supervising Physician Extenders" was published in the October edition of *Diagnostic Imaging*. Tom and **Heather M. Zimmerman** were published in the September edition of *The American Journal of Roentgenology* in an article entitled "The Beginning of the End of Self-Referral?" Tom and Heather also sent a memo entitled "2008 Medicare Physician Fee Schedule Final Rule" to radiology and other health care clients in November. In addition, Tom and Heather wrote a client alert entitled "Elimination of Stark 'On-Site' Interpretation Requirement," which was sent out in November by the American Health Lawyers Association ("AHLA") to some of its members. Tom also was published in the July edition of *The Journal of Nuclear Medicine* in an article entitled "Nuclear Medicine and the Stark Truth: What Are the Rules?"

Kathleen H. McGuan, **Gail L. Daubert** and **Debra A. McCurdy** wrote an article entitled "Medicare's New Policy for Recalled, Replaced Devices," which was published by *HealthLaw 360* in November.

Areta L. Kupchyk, **Ricardo Carvajal**, **Adam S. Bloom, Celeste Letourneau, Kevin S. Madagan** and **Jamie L. Stulin** authored a food and drug client bulletin entitled "The FDA Amendments Act of 2007," which was sent to clients in October.

"CMS Stark II (Phase III) Final Rule," a health care client bulletin by **Kevin R. Barry**, **Gina M. Cavalier**, **Catherine A. Durkin**, **Thomas W. Greeson**, **Paul W. Pitts**, **Karl A. Thallner, Jr.**, and **Heather M. Zimmerman**, was sent to clients in October.

Frederick H. Branding and **Ricardo Carvajal**, along with **Antony B. Klapper**, **Stephen P. Murphy**, **Elizabeth A. Ransom** and **James M. Wood**, contributed to a client bulletin entitled "Recent Chinese Product Safety Recalls – Mitigating Potential Liability Exposure," which was sent to clients in August.

Gail L. Daubert, **Debra A. McCurdy** and **Kathleen H. McGuan** authored a health care client bulletin entitled "Medicare Hospital Inpatient Rule: New Policy for Recalled/Replaced Devices," which was sent to clients in August.

Jason M. Healy and **Kevin R. Barry** wrote a health care client bulletin in August entitled "Ninth Circuit Rules That Provider Reimbursement Review Board May Order Reimbursement of Expenses Not Claimed In Cost Report or Previously Considered by Intermediary."

Joseph W. Metro made a presentation entitled "Year in Review/Preview for Drug Manufacturers" to firm client Boehringer Ingelheim at its U.S. law department meeting. If you are interested in learning more about the presentation, please contact Joe.

Mark G. Pedretti, **Areta L. Kupchyk**, **Kathleen H. McGuan**, **Nicola Maguire** and **Paule Drouault-Gardrat** presented the first installment of our Health Care and Life Sciences Regulatory Update: U.S. and European Markets, Oct. 30. This call will be the first in a series and is designed to be a streamlined update regarding U.S. and European regulatory and legislative developments relevant to companies in the health care and life sciences industries, as well as investment and other firms who have holdings in these sectors. The next call will probably be held in early 2008.

Carol C. Loepere is scheduled to speak at AHLA's Fundamentals of Health Law Conference, which will take place in Chicago Dec. 2–4. Carol will present regarding "Long Term Care/Home Health Care."

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Supreme Court to Rule on Federal Preemption Cases…
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also argued that a requirement in the Michigan statute requiring the plaintiffs to establish a state law finding there was fraud-on-the-FDA which, if known by the FDA, would have prevented approval of the drug was impliedly preempted. *Warner-Lambert* relied on the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Comm.*, 531 U.S. 341 (2001) and the Sixth Circuit's application of the *Buckman* decision in *Garcia v. Wyeth Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004) that fraud-on-the-FDA claims were impliedly preempted by federal law. The district court agreed, and the case was dismissed.

> "The question presented to the Supreme Court by *Riegel* is whether the express preemption provisions of the MDA preempt state-law claims seeking damages for injuries caused by medical devices that received premarket approval."

Reinstating the suit on appeal, the Second Circuit held that when deciding questions of federal law, it was not bound by the Sixth Circuit's decision involving the laws of Michigan. Relying on a presumption against preemption, and contrary to the Sixth Circuit's holding in *Garcia*, the Second Circuit held federal law did not preempt state common law liability through a fraud exception. The Second Circuit distinguished *Warner-Lambert* from *Buckman* by narrowly reading *Buckman* and finding the appellants were not asserting a standalone cause of action for fraud-on-the-FDA, as did the appellants in *Buckman*, but rather, were asserting claims under traditional state tort law. Other district courts and state courts have adopted a similarly narrow approach to *Buckman*. However, as noted in Warner-Lambert's Petition, the Second Court's decision is contrary to holdings rendered by the Third, Sixth, and Ninth Circuits' more functional application of *Buckman*.

Warner-Lambert asserts two potentially far-reaching effects of the issues raised in the case: (1) resolving the circuits' split will impact many cases and the Michigan statute; and (2) a reasoned interpretation of *Buckman*, consistent with the Sixth Circuit's, is essential to avert the dire consequences to the FDA regulatory process that *Buckman* predicted would result from allowing state law fraud-on-the-FDA claims.

Riegel v. Medtronic *(451 F.3d 104 (2d Cir. 2006), U.S. No. 06-179)*

The plaintiffs in *Riegel* brought state law damage claims against Medtronic, for injuries that resulted when the company's coronary angio-plasty catheter burst during a procedure. The plaintiffs alleged design and manufacturing defects implicated an express warranty and inadequate warnings claims, among others. The focus of the inadequate warning claim centered on apparently conflicting information on the product labeling. The labeling stated not to inflate the balloon catheter above eight atmospheres of pressure, but also contained test results for balloon inflations of up to 13 atmospheres. The plaintiffs, therefore, argued inflation above eight atmospheres was acceptable. The district court granted Medtronic's motion for summary judgment on the inadequate warning claims. The Second Circuit found preemption on the basis that PMA imposes device-specific requirements, and state law design defect and inadequate warning claims are specific enough to devices to warrant federal preemption.

The question presented to the Supreme Court by *Riegel* is whether the express preemption provisions of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act preempt state-law claims seeking damages for injuries caused by medical devices that received premarket approval. The Su-

preme Court previously addressed this issue in its 1996 medical device preemption review of *Medtronic Inc. v. Lohr*. 518 U.S. 470 (1996). At issue in *Lohr* was whether the presence of a state law damage remedy for violations of FDA requirements under the 510(k), Premarket Notification (PMN), approval process imposed additional requirements upon medical device manufacturers. In *Lohr*, the Supreme Court held certain state law requirements that parallel FDA requirements, such as a state law damages remedy for violations of FDA requirements for products approved under a 510(k), do not impose additional burdens on device manufacturers, but "merely provide another reason for manufacturers to comply with…federal law." Accordingly, the state requirements did not fall within the intended scope of the federal statute and regulations, and thus, were not preempted. Although the court found no preemption in the *Lohr* case, it left open the issue of whether there could ever be preemption.

Potential Implications of the Supreme Court Decisions

FDA is considered the expert federal public health agency charged by Congress with ensuring that medical products are safe and effective, and that their labeling adequately informs professionals and patients of the risks and benefits of the product and is truthful and not misleading. Courts have traditionally deferred to FDA's interpreting and administering the Food, Drug, and Cosmetic Act.

Inconsistent court decisions regarding the application of federal preemption analysis in state actions for product liability against drug and device manufacturers creates confusion and uncertainty for both FDA and manufacturers. With these two cases, and possibly a third before the Court, the Court has an opportunity to resolve the divisions among the lower courts and to provide much needed guidance in an increasingly inconsistent area of law. The Court also has an opportunity to clarify the law of preemption and to remove the obstacle of state failure-to-warn claims that frustrate the full achievement of FDA's objectives and purposes. Failure to do so will create even greater confusion than currently exists with courts' divergent analyses of the application of federal preemption to the regulation of medical products evaluated and approved by FDA.

In the News

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Daniel A. Cody will present in a panel entitled "Medicare and Medicaid Update" at the ABA Health Law Section 5th Annual Washington Healthcare Summit, scheduled to take place Dec. 3–4 in Washington, D.C.

Ricardo Carvajal is scheduled to provide an "Overview of Food and Drug Law" at the Fundamentals of Food and Drug Law and Regulation Workshop – Understanding How and Why FDA Regulates the Industries. The workshop is scheduled to take place Dec. 10–11 in Washington, D.C.

Gordon B. Schatz is scheduled to speak in San Diego at CBI's 3rd Annual Forum on Medical Device & Diagnostics Reimbursement & Coverage Dec. 11, and will provide an "Overview of the DRG Changes and Medicare's Hospital Inpatient Reimbursement Rates," and will also speak regarding "New Development in Hospital Outpatient APC and Ambulatory Surgical Center Payment Systems."

Health Law Monitor is published by Reed Smith to keep clients and friends informed of developments in health law. It is not intended to provide legal advice to be used in a specific fact situation; the contents are for informational purposes only.

Christie E. Bloomquist and Robert J. Kaufman are the editors of *Health Law Monitor*. Any comments or suggestions can be addressed to Christie at 202 414 9212 or cbloomquist@reedsmith.com, or to Rob at 202 414 9407 or rkaufman@reedsmith.com.

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Reed Smith Health Care Group

Lisa S. Albright	lalbright@reedsmith.com	609 524 2031
Cynthia A. Alcantara	calcantara@reedsmith.com	703 641 4306
Kenneth S. Barr	kbarr@reedsmith.com	202 414 9282
Kevin R. Barry	kbarry@reedsmith.com	202 414 9211
Adam S. Bloom	abloom@reedsmith.com	202 414 9237
Christine E. Bloomquist	cbloomquist@reedsmith.com	202 414 9212
Frederick H. Branding	fbranding@reedsmith.com	312 207 2458
Elizabeth Carder-Thompson	ecarder@reedsmith.com	202 414 9213
Ricardo Carvajal	rcarvajal@reedsmith.com	202 414 9483
Gina M. Cavalier	gcavalier@reedsmith.com	202 414 9288
Daniel A. Cody	dcody@reedsmith.com	415 659 5909
J. Ferd Convery, III	jconvery@reedsmith.com	609 514 5940
Gail L. Daubert	gdaubert@reedsmith.com	202 414 9241
David E. Dopf	ddopf@reedsmith.com	609 524 2030
Catherine A. Durkin	cdurkin@reedsmith.com	202 414 9229
Thomas C. Fox	tfox@reedsmith.com	202 414 9222
Thomas W. Greeson	tgreeson@reedsmith.com	703 641 4242
Scot T. Hasselman	shasselman@reedsmith.com	202 414 9268
Jason M. Healy	jhealy@reedsmith.com	202 414 9245
Robert J. Hill	rhill@reedsmith.com	202 414 9402
Robert J. Kaufman	rkaufman@reedsmith.com	202 414 9407
Henry R. King	hking@reedsmith.com	609 514 5941
Murray J. Klein	mklein@reedsmith.com	609 520 6022
Julia Krebs-Markrich	jkrebs-markrich@reedsmith.com	703 641 4232
Areta L. Kupchyk	akupchyk@reedsmith.com	202 414 9362
Celeste Letourneau	cletourneau@reedsmith.com	202 414 9260
Carol C. Loepere	cloepere@reedsmith.com	202 414 9216
Kevin M. Madagan	kmadagan@reedsmith.com	202 414 9236
Cassia M. McCamon	cmccamon@reedsmith.com	202 414 9225
Debra A. McCurdy	dmccurdy@reedsmith.com	703 641 4283
Kathleen H. McGuan	kmcguan@reedsmith.com	202 414 9278
Frances Meehan	fmeehan@reedsmith.com	312 207 6468
Joseph W. Metro	jmetro@reedsmith.com	202 414 9284
Rahul Narula	rnarula@reedsmith.com	202 414 9270
Robert K. Neiman	rneiman@reedsmith.com	312 207 6546
Karen L. Palestini	kpalestini@reedsmith.com	609 520 6037
Lorin E. Patterson	lpatterson@reedsmith.com	703 641 4368
Paul W. Pitts	ppitts@reedsmith.com	415 659 5971
Steven B. Roosa	sroosa@reedsmith.com	609 514 5983
Brad M. Rostolsky	brostolsky@reedsmith.com	215 851 8195
Gordon B. Schatz	gschatz@reedsmith.com	202 414 9259
Amie E. Schaadt	aschaadt@reedsmith.com	215 851 8106
Paula M. Schenck	pschenck@reedsmith.com	215 851 8100
Wendy H. Schwartz	wschwartz@reedsmith.com	212 549 0272
Tamara V. Scoville	tscoville@reedsmith.com	202 414 9239
Nancy A. Sheliga	nsheliga@reedsmith.com	804 344 3439
Keith T. Shiner	kshiner@reedsmith.com	703 641 4221
Abraham J. Stern	astern@reedsmith.com	312 207 6465
Jamie L. Stulin	jstulin@reedsmith.com	202 414 9262
Thomas H. Suddath, Jr.	tsuddath@reedsmith.com	215 851 8209
Karl A. Thallner, Jr.	kthallner@reedsmith.com	215 851 8171
Eugene Tillman	etillman@reedsmith.com	202 414 9244
Heather M. Zimmerman	hzimmerman@reedsmith.com	703 641 4352

Contributors To This Issue

Cynthia A. Alcantara
Falls Church
703 641 4306
calcantara@reedsmith.com

Frederick H. Branding
Chicago
312 207 2458
fbranding@reedsmith.com

Gail L. Daubert
Washington, D.C.
202 414 9241
gdaubert@reedsmith.com

Catherine A. Durkin
Washington, D.C.
202 414 9229
cdurkin@reedsmith.com

Robert J. Kaufman
Washington, D.C.
202 414 9407
rkaufman@reedsmith.com

Celeste Letourneau
Washington, D.C.
202 414 9260
cletourneau@reedsmith.com

Kevin M. Madagan
Washington, D.C.
202 414 9236
kmadagan@reedsmith.com

Robert K. Neiman
Chicago
312 207 6546
rneiman@reedsmith.com

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