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CRIMINAL AND CIVIL LIABILITY TO PHYSICIANS AND OTHER HEALTH CARE PROVIDERS FOR THE OFF-LABEL MARKETING OF FDA-APPROVED DRUGS OR DEVICES: AN EMERGING TREND?

By: Kevin E. Raphael, Esq. and Shannon L. Voll, Esq.

The Food and Drug Administration ("FDA") is empowered to determine whether any given drug or medical device will be approved for sale in the United States. The FDA does not, however, have the power to regulate the practice of medicine. For example, once the FDA approves a drug for a particular use, physicians are free to use the drug for any purpose. This practice is routine among physicians. As long as individual physicians are using drugs or devices based on their professional judgment that such use is in the best interest of their patients, the federal government has no right to interfere. This is commonly referred to as "off-label" use.

Consequently, pharmaceutical companies were quick to develop marketing strategies to promote drugs for off-label use. However, the FDA does have the authority to regulate how pharmaceutical and device companies market their products, and has prohibited, in most circumstances, the marketing of drugs or devices for their "off-label" uses. Over the past several years, the pharmaceutical companies have paid a heavy price for this illegal practice, becoming the target of criminal investigations, attendant negative publicity and uncertainty, and hundreds of millions of dollars in settlements.

In addition, the False Claims Act has been used against pharmaceutical companies, resulting in the payment of vast sums of money to the federal government and the "whistleblowers" who initiated the lawsuits. More recently, the government has turned its attention to medical device companies, investigating both their marketing of unapproved uses for their products, and their financial relationships with physicians who use their products. The U.S. Attorney's Office for the District of New Jersey recently settled with five of the largest orthopedic medical device companies for their improper marketing of FDA-approved devices, with four of the five paying hundreds of millions of dollars in criminal and civil penalties and fines.

Physicians and other health care providers, however, should not assume that the federal government will limit its criminal and civil investigations to only the pharmaceutical and device companies. The last several years have evidenced an emerging, and possibly growing, trend by the government and private health insurance companies: to pursue individual physicians and other health care providers for violating laws and regulations concerning the marketing of FDA-approved drugs and devices.

The Fine Line Between Off-Label Use and Off-Label Promotion

Off-label use is widespread. A study released in May 2006 reported that in 2001, roughly two-thirds of prescriptions written for six common drugs were for off-label use. A 2004 study involving pediatric patients (those 18 and younger) showed that almost 80 percent of pediatric patients have been treated with at least one off-label drug.

While a physician's, or other health care provider's, right to use drug or device for off-label uses is relatively clear-cut, their right to promote the off-label use is not without limits. Yes, doctors can, and indeed frequently do, confer with colleagues about their successes with the off-label use of a particular device or drug. Yet, what if the physician is conferring with his or her colleagues during a conference paid for by the drug or device company? What if the physician is under contract with the drug or device company to perform research or consulting services, and also confers with his or her colleagues about the off-label uses of the company's drugs or devices?

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Mandatory Rules for Pennsylvania Medical Facilities for Reporting Medical Errors, Adverse Events and Device Failures

By: Michael A. Morse, Esq.

News stories recounting errors occurring during surgical or other medical procedures are nothing new. Recent reports of the failures of outpatient care at the Walter Reed Army Medical Center are just one example. In 1999, the national Institute of Medicine (IOM) reported as many as 98,000 Americans die each year from medical errors, and that approximately 1 million experienced significant adverse events resulting in as much as $29 billion in annual financial costs.

In response to these catastrophic, systemic failures of care, a patchwork of federal and state regulations have arisen that mandate that hospitals and other health care providers report medical errors, adverse events, near misses and device failures. Failure to comply with these federal and state mandatory reporting rules can have far reaching consequences, including potential criminal, civil and licensing penalties. In addition, failing to report medical errors can serve as a catalyst for increased scrutiny by federal and state regulators, and can spur whistleblower lawsuits under federal and state false claims acts.

Despite these potentially devastating consequences, many health care providers are unaware of the various federal and state mandatory requirements for reporting medical errors, adverse events, near misses and device failures. Moreover, many health care providers who are aware of their reporting obligations have failed to adopt adequate policies and procedures to ensure compliance with these myriad, and often conflicting, federal and state regulations.

The risks to health care providers caused by these compliance failures continues to grow as federal and state regulators, not to mention the media and the public, pay increasing attention to quality of care issues. In fact, some government regulators are implementing innovative measures to test for compliance with mandatory reporting obligations, including data mining and comparing death certificates to reports of medical errors. Given this growing attention to quality of care, health care providers must act quickly to ensure that they are fully complying with the various federal and state rules for reporting medical errors.

Federal System - Patient Safety and Quality Improvement Act

In 2005, the U.S. Congress enacted the Patient Safety and Quality Improvement Act of 2005 ("PSQIA"), to attempt to establish some degree of nationwide uniformity in the reporting of medical errors and adverse events. The PSQIA creates a comprehensive system through which health care providers can voluntarily submit patient safety information, which is then to be analyzed to determine the causes of, and eventually prevent, medical errors. The PSQIA also provides, for the first time, a broad federal statutory privilege and confidentiality protection covering the reporting of medical errors (that are made in accordance with the PSQIA).

Although the PSQIA was enacted in July of 2005, it is still awaiting the adoption of final regulations (proposed in early 2008) by the Department of Health and Human Services (HHS) before it can properly take effect. Nonetheless, the federal government is predicting that 45 percent of the hospitals in the U.S. will participate in the PSQIA's voluntary reporting network by 2012.

Federal System - Mandatory Reporting Regimes

A number of mandatory federal reporting regimes predate the PSQIA. These regimes are highly specialized and focused not on medical errors in general, but on regulating and monitoring narrow areas of health care. The finely circumscribed nature of these regimes can make compliance difficult without a proper understanding of what areas these regimes regulate.

Medical Device Reporting

Congressional regulations require that medical device "manufacturers" and "device user facilities" report deaths or serious injuries that result from the use of medical devices. Device user facilities are required to report these adverse events within ten business days to the Food and Drug Administration (FDA) Center for Devices and Radiological Health and, if the manufacturer's identity is known, to the manufacturer as well. Because of the broad definition of manufacturer in this context, it is important for any device user, including hospitals and other medical facilities, to carefully determine whether it might also be a device manufacturer for reporting purposes.

Vaccine Adverse Event Reporting System

The Vaccine Adverse Event Reporting System (VAERS) accepts reports from health care providers, manufacturers and the public regarding adverse events associated with U.S. licensed vaccines. Manufacturers and health care providers are required to report any adverse events through VAERS, with sanctions for failure to report generally limited to license revocation or similar disciplinary action.

Current Good Tissue Practice Regulations

Human cells or tissue, other than blood, intended to in any way be transferred into a human being is regulated by the FDA as a human cell, tissue, and cellular and tissue-based product, or "HCT/P." HCT/P "establishments" are required to investigate adverse reactions involving any communicable disease associated with HCT/P it distributed and to report any such reactions that are fatal, life-threatening, result in permanent impairment or harm, or require medical or surgical intervention.

Blood and Blood Product Manufacturing Errors

Blood and blood-product manufacturers are required to report any event related to the manufacture (including testing, processing, packing, labeling or storage) or the holding or distribution of blood or blood products which represents a deviation from good manufacturing practice or standards, or represents an unexpected event that may affect the safety, purity or potency of the product. These reports must be made to the Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality no more than 45 calendar days from the date of discovery of information reasonably suggesting that a reportable event has occurred.

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Hospital Mergers Receive Closer Antitrust Scrutiny from Federal Trade Commission

By: Bryan S. Neft, Esq.

Throughout the 1990s, the Federal Trade Commission ("Commission") had little success challenging hospital mergers that it claimed substantially lessened competition in violation of federal antitrust laws. As a result, in 2002, the Commission restructured its litigation unit and began a retrospective review of hospital mergers to determine if any of the mergers had, in fact, reduced competition.

The retrospective review produced a single challenge to a hospital merger: the 2000 merger of Highland Park Hospital with Evanston Hospital and Glenbrook Hospital, three hospitals in the affluent northern suburbs of Chicago, which created the Evanston Northwestern Healthcare Corporation ("ENH"). In 2004, the Commission filed an administrative complaint against ENH, claiming that the merged entity had substantially lessened competition in violation of Section 7 of the Clayton Act.

In 2006, an administrative law judge issued lengthy findings of fact and conclusions of law that the three hospitals had been able to substantially raise prices charged to managed care organizations (MCOs) for general inpatient acute care services, and were able to sustain those prices within the relevant geographic market encompassing seven local hospitals, including ENH's three. The ALJ ordered ENH to divest itself of Highland Park Hospital.

In 2007, the Commission issued an opinion affirming the rulings that the merger substantially lessened competition. It did so by holding that the geographic triangle encompassing ENH's three hospitals constituted the relevant geographic market. Although the Commission found antitrust violations, it vacated the ALJ's remedy of divestiture and instead required the ENH hospitals to negotiate its MCO contracts independently and without sharing information.

Paramount to the Commission's decision were communications of senior officers of Evanston Hospital expressly detailing that a primary motivating factor of the merger of Highland Park with Evanston and Glenbrook Hospitals was to enhance its negotiating leverage with MCOs. These communications, coupled with evidence that subsequent negotiations with many (but not all) managed care organizations resulted in substantial increases in contracted rates for hospital care, were enough for the Commission to find that the merger had resulted in a non-transient increase in prices.

In defense, ENH claimed that the price increases resulted because Highland Park Hospital had reimbursement rates for hospital care that were below market pricing and the renegotiations brought them to the level of competitive pricing. The Commission rejected this argument, finding that there was no credible evidence that Highland Park's previous reimbursement rates resulted from anything other than competitive factors.

> The Commission found the evidence of anticompetitive intent and effects to be self-evident.

ENH also argued that the higher reimbursement rates were justified by post-merger advancements in quality of care at Highland Park. The commission rejected this defense as well, finding that there was no evidence that the enhanced quality measures rebutted the evidence of anticompetitive effects of the merger. As a practical matter, the Commission found the evidence of anticompetitive intent and effects to be self-evident, causing the Commission to discount the rationales that ENH advanced for the higher prices.

The most noteworthy rulings of the Commission came in the market definitions found to exist in order to support its findings of antitrust violations from the merger. First, the Commission found the relevant product market to include *all* general inpatient acute care services. Second, it defined the geographic market as ENH itself and the geographic triangle encompassing its three hospitals.

The Commission defined the relevant geographic market as the triangle formed by ENH's three hospitals by looking to the anticompetitive effects of the merger. Thus, the Commission concluded that if ENH was able to raise prices for hospital reimbursement rates, then the hospitals themselves must be deemed a relevant geographic market. Although such a narrow rendering of the relevant geographic market was non-existent in prior hospital merger analysis, the definition most likely reflects the Commission's concern, based on the evidence, that ENH successfully raised prices to a number of MCOs with the intent to do so. The direct evidence, therefore, was used to formulate the relevant geographic market.

Finally, the Commission's decision, for the first time, gauged the anticompetitive effects of the merger by "following the money." In traditional hospital merger analysis, the courts have focused on patient flow data into and out of the alleged geographic market to determine if the defendant maintains market power. The Commission rejected use of this analysis, known as the "Elzinga-Hogarty" test, primarily because of testimony of Professor Kenneth Elzinga that his test was not an appropriate method to define the geographic markets in hospital merger cases. According to Dr. Elzinga, price is not usually a factor that patients use to determine where to obtain hospital care, and that the focus of the antitrust analysis must be on the MCOs that foot the bill for hospital care. Professor Elzinga testified,

> [T]here's a wedge between the consumption of the service and the person who decides where the service will be consumed and then some other party actually paying for the service, and consequently, the usual market analysis of goods and services … in response to price incentives really doesn't fit. And so it follows in my view that looking at the flow of patients really doesn't help you define the contours of a relevant geographic market area because the patients who are moving are not necessarily moving in response to price incentives.

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M-Care Infection Control: A Litigation Threat?

By: Paul K. Vey, Esq.

The Pennsylvania legislature recently passed amendments to Act 13, the Medical Care Availability and Reduction of Error Act. Among the amendments is a chapter dealing with health care-associated infections and detailing the requirements that health care facilities (defined as "a hospital or nursing home licensed or otherwise regulated to provide health care services under the laws of this Commonwealth") must follow. The statute requires reporting to the Department of Health, including patient-specific data for health care-associated infection.

At a recent medical malpractice seminar by the Pennsylvania Trial Lawyers Association, an organization comprised largely of attorneys who represent plaintiffs, it was suggested by one of the speakers that the failure of a health care facility to follow the new requirements embodied within the M-Care Infection Control Amendments would be admissible in a trial against the health care facility to prove the facility's negligence *per se*, or at least for purposes of establishing an inference that the health care facility was negligent.

This approach reflects a growing trend on the part of plaintiffs' counsel across the nation to attempt to utilize a regulatory framework designed to improve overall patient care as a sword in proving a health care facility's negligence in individual cases. These theories seek to establish a private cause of action and/or prove the alleged negligence of a health care facility using the Medicare/Medicaid Acts (specifically, the Omnibus Budget Reconciliation Act of 1987, the Healthcare Facilities Act, the Federal Nursing Home Reform Law and the Social Security Act, among others).

Hospitals and nursing homes are likely to find themselves faced in the coming months with negligence claims that include reference to a variety of regulations promulgated pursuant to these various statutes and regulations as a basis for alleging that statutory or regulatory non-compliance either is evidence of negligence or proof of negligence (negligence *per se*).

To this point, Pennsylvania appellate courts have not ruled on application of these statutes as a basis for a cause of action in negligence. However, the lower courts have been called upon to address issues that fall into two broad categories: First, whether the absence of a statutorily-mandated program designed to improve patient safety gives rise to an *independent* cause of action; and, second, even if an independent cause of action does not arise, whether the failure to comply with those regulations is admissible in an individual claim. In each category, some lower courts have ruled that the plaintiff may introduce such evidence with an appropriate legal foundation.

Pennsylvania appellate courts have not ruled on application of these statutes as a basis for a cause of action in negligence.

The recent M-Care Amendments provide that the development of an internal infection control plan "shall" be established for the purpose of improving the health and safety of patients and health care workers. Under the plaintiffs' theory, if no plan is established or, alternatively, if a plan is established and then largely is ignored, a patient who develops MRSA, a hospital-based infection, or even bed sores is likely to make a claim that the facility is negligent *per se*.

Similarly, the new amendments require that infections be reported. Failure to report such an infection will allow a plaintiff's attorney to argue that a "cover-up" was the reason for the failure to report the infection. The rationale for asserting the application of such regulations to an individual plaintiff's claim appears, for example, in the Healthcare Facilities Act penalty provisions, which states two purposes: first, to protect and promote public health and welfare and, second, to establish "minimum standards." This latter reference gives rise to the plaintiffs' argument that the regulations can be utilized to establish a duty to patients, not simply to regulatory agencies.

Across the nation, the question of whether or not these state infection control (and other) regulations can be utilized by plaintiffs to enhance an individual personal injury case often turns on the question of whether or not the regulatory provisions suggest that the facility's duty runs to the patient, rather than simply to the accrediting or licensing organization within the government.

The argument to be made by defense counsel for its clients in Pennsylvania under the new M-Care Amendments is that the statutory framework speaks in terms of "guidelines" and the development of "effective measures" for detection, control and prevention of health care-associated infections, but are not intended to be the measure by which an individual case is to be determined.

And, while effective arguments can be made that the new M-Care Amendments should not serve as ammunition for the plaintiffs' claims, one of the most effective defenses to such claims is the implementation and application of thorough infection control monitoring standards and proper reporting. Effective program and reporting measures on the part of health care facilities will make it far less likely that reviewing courts will feel compelled to examine policy considerations embodied in the applicable patient safety statutes and regulations and, in turn, less likely that plaintiffs' attorneys can use the regulations to their advantage.

In short, compliance with the M-Care mandates is the key weapon in your defense counsel's arsenal when the plaintiffs' lawyer comes calling.

For more information about the M-Care Amendments and its implications, please contact Paul K. Vey at (412) 263-2000 or via e-mail at PVK@PIETRAGALLO.com.

Update: Federal Pre-Emption of State Tort Claims Involving Medical Devices and Pharmaceutical Products

By: Martha S. Helmreich, Esq.

This year, there have been several significant decisions concerning the pre-emption of state tort claims involving medical devices and pharmaceutical products. Two offered decisive victories for the manufacturers. The U.S. Supreme Court will hear argument on a third involving pre-emption of tort claims concerning drugs during its upcoming October term. To date, these decisions have evidenced a trend to expand pre-emption of state tort claims, based on the Food and Drug Administration's ("FDA") regulatory authority over medical devices and pharmaceutical products.

Pre-Emption of Claims Involving Devices

In 1996, the U.S. Supreme Court held that state law claims sounding in negligence and strict liability arising from the failure of a Medtronic pacemaker, a Class III medical device subject to the "substantial equivalency process" [§510k] of the Medical Device Act ("MDA"), were not pre-empted by §360k of the MDA. Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Ct. 2240 (1996).

Since its decision in Lohr, the Supreme Court had declined to grant certiorari in other cases addressing this issue. This changed last year when the Court heard argument in Riegel v. Medtronic, ___ U.S. ___, 128 S. Ct. 999 (2008). In Riegel, the Court, interpreting and applying §360k, held: 1) that the FDA's Pre-Market Approval ("PMA") process, unlike the "substantial equivalence" process, imposes federal, device-specific requirements on devices subject to the that process; and 2) that state common law claims "impose requirements" under the ordinary meaning of that term.

Accordingly, state tort claims are now expressly pre-empted to the extent the state tort claims seek to impose requirements for a Class III device "different from, or in addition to" the requirements imposed by the FDA. The Riegel decision does not pre-empt state law claims premised on a violation of FDA regulations or FDA requirements set forth in the PMA process. In other words, state law tort claims that allege the existence of duties "parallel to" the requirements established by the FDA in the PMA process, such as manufacturing defect claims, would not be pre-empted.

The FDA, both in its amicus briefs to the Supreme Court in Riegel, and in its express policy positions, has signaled a strong pro-pre-emption position concerning medical devices. The Riegel decision appears to signal both the current Court's willingness to support federal regulation of the health and safety of pharmaceutical and medical products over the "regulation" created by state tort law, and the FDA's current push to effect and promote federal regulation in this area.

Pre-Emption of Claims Involving Drugs

Although the FDA has been regulating drugs since the early twentieth century, there are no express statutory provisions within the Federal Food, Drug and Cosmetic Act ("FDCA") concerning the pre-emption of tort claims involving drugs. The FDA, however, has been vocal in its views concerning the expansion of federal pre-emption in this arena. Currently, the FDA's position, with respect to its new drug labeling rules, is that "under existing [implied] preemption principles, FDA approval of labeling under the act [FCDA], whether it be in the old or new format, pre-empts conflicting or contrary state law" and further that the "FDA interprets the act to establish both a 'floor' and a 'ceiling'" for labeling requirements. 71 FR 3922, 3934-3936, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" (January 24, 2006) (comment 13).

According to the FDA, as "the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading," the FDA carries on comprehensive scientific product evaluations and carefully controls content of labeling. The FDA has repeatedly expressed concern that its regulatory authority can be threatened by state product liability lawsuits.

The U.S. Supreme Court addressed the issue of federal pre-emption over tort claims involving drugs in its recent decision in Warner-Lambert Co. v. Kent, No. 06-1498. At issue in Kent was a Michigan statute that generally prohibits common law product liability claims against drug makers "if the drug was approved for safety and efficacy" by the FDA "and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller."

However, the Michigan statute specifically provides that such "immunity" does not apply if the defendant withholds information from, or makes misrepresentations to, the FDA. In Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001), the Supreme Court ruled that plaintiff's fraud-on-the-FDA claims were impliedly pre-empted by federal law. However, in Kent, the Second Circuit held that the Buckman pre-emption did not apply to the immunity defense found in the Michigan statute. On March 3, 2008, an equally divided Supreme Court affirmed the Second Circuit *per curiam*, thus leaving to another day a further decision on the pre-emptive scope of the FDCA.

That day may come in Levine v. Wyeth, No. 06-1249, a case from Vermont, to be argued in October. Levine involves state law claims for failure to provide adequate warnings on a prescription drug, Phenergan. The Vermont courts rejected Wyeth's implied, conflict pre-emption defense, which was based in part on Wyeth's contention that it had submitted a more "adequate" warning to the FDA for approval, but the FDA rejected the change because it did not favor strengthening the warning. The Vermont Supreme Court found that Wyeth could have provided the additional, stronger warning plaintiff argued for without prior FDA approval and also that federal labeling requirements "create a floor, not a ceiling, for state regulation," a conclusion it asserted was shared by a "significant majority" of other courts. The Supreme Court's decision in Levine will further define the application of the pre-emption doctrine in state tort claims concerning adequate warnings on drug labels.

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These and similar situations may indeed expose the individual physician to criminal and civil liabilities, particularly given the government's emerging focus on investigating medical device companies' marketing efforts and relationships with physicians.

Criminal Prosecution of Individual Physicians or Other Health Care Providers for Off-Label Marketing

The government has been very active in past years investigating and prosecuting physicians and other individuals for their roles in the off-label marketing of FDA-approved drugs and devices. Several examples serve as cautionary tales.

Dr. Peter Gleason believed that Xyrem, approved by the FDA to treat patients with narcolepsy, was also an effective treatment for patients suffering from insomnia and severe depression, conditions not approved by the FDA. Dr. Gleason's off-label prescribing caught the attention of Xyrem's manufacturer, Orphan Medical. Inc. At the request of Orphan, Dr. Gleason started speaking to other physicians about his experiences with Xyrem, specifically its off-label uses. Orphan paid Dr. Gleason for his time.

In April 2005, after a tip from a whistleblower inside Orphan Medical, the government began investigating Dr. Gleason and in April 2006, the U.S. Attorney's Office for the Eastern District of New York filed a criminal indictment against Dr. Gleason. The government alleges that Dr. Gleason conspired with Orphan sales representatives to promote off-label uses of Xyrem in violation of the Food, Drug, and Cosmetic Act.

In its indictment, the government attempts to portray Dr. Gleason as a puppet for the drug manufacturer, rather than an unbiased physician exercising his right to practice medicine freely. The government bases this allegation, in part, on the fact that Dr. Gleason received tens of thousands of dollars from Orphan. The government also alleges that Dr. Gleason told physicians to provide an incorrect diagnosis to the insurance companies to ensure payment for the off-label use.

In July 2007, Jazz Pharmaceuticals, successor to Orphan, agreed to pay $20 million to settle civil and criminal proceedings concerning its off-label marketing of Xyrem. Charges against Dr. Gleason are still pending.

Further, on March 18, 2008, W. Scott Harkonen, M.D., the former CEO of biopharmaceutical firm InterMune Inc., was indicted for his alleged role in illegally promoting one of the company's drugs for off-label use. The government alleges that Dr. Harkonen proceeded with an extremely successful marketing campaign that promoted the drug Actimmune as a safe and effective treatment for idiopathic pulmonary fibrosis (IPF), even though early studies of the drug to treat IPF had failed. The government claims that sales of the drug increased from $11 million to $141 million between 2000 and 2003, and contends that the off-label promotion was a scheme to defraud doctors and patients.

InterMune had previously agreed to pay over $36.9 million to resolve civil and criminal allegations that it illegally promoted Actimmune for off-label use.

Finally, the Seventh Circuit recently upheld the conviction of two executives of a medical device company, AbTox, who, among other things, promoted AbTox's FDA-approved sterilizer of medical instruments for unapproved uses. United States v. Caputo, 517 F.3d 935 (7th Cir. 2008). The Court upheld the two executives' sentences of six and ten years, respectively, but remanded to the District Court to recalculate restitution owed to the hospitals and other entities that purchased AbTox's sterilizer.

The Civil Risk to Physicians or Other Health Care Providers Who Engage in Off-Label Marketing/Promotion

The federal and state governments, through administrative means and/or the federal or individual state false claims acts have pursued, and will continue to pursue, civil sanctions against physicians, other health care providers, and executives for the off-label marketing of FDA-approved drugs or devices. Further, insurance companies are increasingly aggressive in their attempts to recover monies paid to health care providers. In turn, they are increasingly willing to pursue civil actions against providers to recover those monies, including the use of state insurance fraud statutes that provide an affirmative right of action to insurance companies. Off-label marketing allegations provide an avenue by which insurers can pursue health care providers. There has been at least one action commenced under this theory.

Dr. David Longmire, an Alabama neurologist, discovered that his use of Neurontin for the FDA-approved use of treating seizures had the non-indicated effect of reducing pain. He told his colleagues about his findings and soon Parke-Davis, the division of Warner-Lambert responsible for Neurontin, was paying Dr. Longmire to share his findings with other health care professionals.

Warner-Lambert (now owned by Pfizer) paid more than $430 million to settle criminal and civil liabilities related to paying physicians to promote Neurontin for off-label use. After the settlement, private insurers began suing Warner-Lambert, and Dr. Longmire was named as an individual defendant in a suit filed by Blue Cross and Blue Shield of Alabama (BCBS). BCBS alleged that Dr. Longmire encouraged physicians to prescribe Neurontin more frequently than they otherwise would have, costing BCBS millions of dollars in improper reimbursements. The case is still pending.

Conclusion

The increasing number of criminal and civil investigations by the government against individual physicians, company executives and other health care providers for the marketing of drugs and devices off-label are a warning that these individuals should be wary of their marketing activities. Caution is especially warranted when the physician or other health care provider engages in a financial relationship with the drug or device company whose product the physician or health care provider advocates for off-label use.

Further, in discussions concerning off-label use, these individuals should ensure that all statements regarding off-label usage are accurate and supported by published data. When physicians begin to promote the drugs or devices they are using, the lines get blurred and both consumers and the government may begin to wonder: is the physician's decision to promote and/or use the drug or device for an off-label use influenced by promising medical results, or rather the promise of a new, highly-lucrative income as a guest speaker? Physicians and other health care providers who are not cautious in their off-label promotional activities risk being perceived as putting their own greed ahead of the welfare of their patients. Worse, they risk becoming the subject of a government investigation, or the defendant in a civil action.

For more information, please contact Kevin E. Raphael at (215) 320-6200 or via e-mail at KER@PIETRAGALLO.com, or Shannon L. Voll at (412) 263-2000 or via e-mail at SLV@PIETRAGALLO.com.

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Opinion, at 77. Because ENH did not challenge the Commission's effort to attack the Elzinga-Hogarty test at the hearing of the case, there is no meaningful way for the practitioner to assess Dr. Elzinga's conclusions. His analysis is subject to criticism for having ignored the underlying reality, which was never shown, that the MCO subscriber and employer ultimately determine whether an MCO is competitive only if it includes the ENH hospitals in its network of hospitals.

Enforcement Commission's Ruling

Only a week prior to the completion of this article, on April 24, 2008, did the Commission issue its final order. That order details the protocols that ENH must implement to ensure that Highland Park negotiates its contracts separately and independently from the other two hospitals. Notably, the order requires the hospitals to reopen negotiations with each and every managed care organization (excepting Medicare and Medicaid) that wishes to do so. Moreover, the order requires the hospitals to negotiate both inpatient and outpatient services together even though the relevant product market in the antitrust analysis included only inpatient services. The Commission reasoned that the practice among hospitals and managed care organizations is to negotiate both as a package, and to order them to be separately negotiated would ignore the realities of the market.

The order also requires Highland Park to establish a negotiating team separate from the other two hospitals with a firewall between them. If a managed care organization desires to negotiate with all of the ENH hospitals together, then a third team needs to be established to address those issues, without any involvement of the individual hospital teams.

Practical Impact of Commission Ruling

The long-term effects of the ENH decision are difficult to predict. Presently, as this article goes to publication, it is unknown whether ENH will appeal the Commission's ruling. Even without an appeal, the ENH decision is based, in several respects, on unconventional analysis. These issues include a broadly-defined product market and a narrowly-defined geographic market, which excluded a geographic area encompassing other hospitals that ostensibly compete with the ENH hospitals. Moreover, although ENH was able to raise prices with some MCOs, it was unable to raise prices with its largest contracting MCO, Blue Cross/Blue Shield, demonstrating that the evidence of market power may not have been as compelling. With all of these questions concerning the analysis, the decision may not serve as precedence for future challenges unless the FTC takes an increasingly proactive stance in challenging hospital mergers through court challenges or its own administrative channels.

The Commission's decision is also likely to have little effect on pre-merger challenges, which will still need to rely on patient flow data, in addition to evidence of anticompetitive conduct, as the only predictive measure of whether a hospital merger creates market power.

Moreover, if the Commission's ruling stands, it remains to be seen if the ENH hospitals would be able to comply with the ruling, complete with mandated Chinese walls that keep the negotiating teams from relying on each other's information. Such a goal may be unreachable when the hospital's management controls the purse strings and the sources of information.

Nonetheless, merging hospitals are now on notice that anticompetitive mergers may be challenged well after the merger is consummated. Health care providers are also on notice that any sign of intent to increase prices as a result of the merger may constitute the strongest evidence of intent to monopolize. Accordingly, hospital management should be cautious about its communications whenever an opportunity for merger arises. One way to shield such information may be through the effective use of counsel to direct any antitrust analysis. Finally, those challenging the mergers are likely to look to MCOs to provide evidence of the predicted effects of a proposed merger on their rates.

For more information, please contact Bryan S. Neft at (412) 263-2000 or via e-mail at BSN1@PIETRAGALLO.com.

David P. Franklin Rejoins Pietragallo as Partner

David P. Franklin has rejoined Pietragallo as a partner based in the Pittsburgh office.

Mr. Franklin is a member of the firm's business group. He has considerable experience in both general corporate work and litigation, and currently focuses his practice in general corporate counseling and advisory services, as well as mergers & acquisitions. He had been a partner with the Pittsburgh office of Reed Smith. Prior to joining Reed Smith in 1999, Mr. Franklin had been an associate with Pietragallo, starting with the firm in 1992.

"David, a Pittsburgher true and through, is an excellent lawyer and we are happy to have him rejoin our firm. He has remained a friend of our lawyers through the years and we enthusiastically welcome him back. His skills and expertise in both general business matters and complex corporate transactions strengthen our business group," said William Pietragallo II, managing partner of Pietragallo.

Mr. Franklin is regularly asked to coordinate the in-house transition of legal operations of target companies following acquisitions and mergers. He also counsels clients in the negotiation and drafting of complex contracts, including master service agreements, consulting arrangements, joint venture agreements, supply and distribution agreements, and product development agreements. In addition, he has represented clients in the negotiation and drafting of stadium and arena naming rights.

Mandatory Rules for Pennsylvania Medical Facilities continued from page 3

Deaths Related to Patient Restraint or Seclusion

The Centers for Medicare and Medicaid Services ("CMS") requires hospitals, as part of the Medicare Conditions of Participation, to report to their CMS any patient death that occurs while the patient is restrained or in seclusion, within 24 hours after the patient has been removed from restraint or seclusion, and within one week after restraint or seclusion where it is reasonable to assume that the patient's death resulted in part from restraint or seclusion.

Pennsylvania's Mandatory Rules for Reporting of Medical Errors

Pennsylvania currently has one of the most comprehensive and expansive mandatory reporting requirements in the United States. Pennsylvania's mandatory reporting system is unique in that it requires the reporting not only of medical errors and adverse events, but also near misses, otherwise known as an "incident." In particular, Pennsylvania requires that all licensed hospitals, ambulatory surgical facilities, birthing centers and certain abortion facilities report what is defined as "serious events", "incidents" and "infrastructure failures." A "serious event" is an event, occurrence or situation involving the clinical care of a patient in a medical facility that either results in death or jeopardizes patient safety and results in an unanticipated injury that requires additional health care services to be provided to the patient. An "incident" is an event, occurrence or situation which could have injured the patient, but did not develop into a "serious event." An "infrastructure failure" is an "undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety."

Serious events must be reported to the Pennsylvania Department of Health and the Patient Safety Authority, established by the M-CARE statute, within 24 hours of the medical facility's confirmation of the serious event. Reports of incidents, by contrast, must be made within a time and manner prescribed by the Patient Safety Authority. Reports of infrastructure failures must be made to the Department of Health within 24 hours of the medical facility's confirmation or discovery of the failure.

A failure to report a serious event or an infrastructure failure is a violation of the Health Care Facilities Act. In addition to any penalty imposed under that statute, a medical facility that fails to report a serious event or an infrastructure failure may be subject to an administrative penalty of $1,000 per day imposed by the Department of Health.

Consequences of Reporting or Failing to Report Medical Errors

In addition to the penalties described above, failure to comply with mandatory reporting statutes can trigger other consequences, including being a catalyst for larger regulatory investigations. One possible consequence of failing to report medical errors that is not facially obvious is prosecution under the federal False Claims Act. Federal prosecutors have used the false claims act to address failures in quality of patient care under the theory that Medicaid and Medicare regulations require quality medical care as a precondition to payment. A failure to report medical errors can, in turn, reinforce a "quality-of-care" false claims case by demonstrating knowledge of quality-of-care problems or that the hospital made a false certification to the government relating to the quality-of-care being provided to federally insured patients.

Given the increasing attention that the public, media and government regulators are paying to failures of care, compliance with the myriad of federal and state mandatory reporting rules is essential for all hospitals and health care providers. Those providers who have adopted some form of reporting system should review their procedures to ensure they are accounting for all of the federal and state reporting requirements and are prepared for the increasing public and private scrutiny of quality of care.

For more information, please contact Michael A. Morse at (215) 320-6200 or via e-mail at MAM@PIETRAGALLO.com.

Update: Federal Pre-Emption of State Tort Claims continued from page 6

The Third Circuit recently addressed this issue in Colacicco v. Apotex, 2008 U.S. App. LEXIS 7463, a 2-1 decision involving a class of anti-depressants ("SSRIs"), specifically Paxil, Zoloft and a generic version of Paxil, all of which bore or were accompanied by FDA-approved labels. In Colacicco, the Third Circuit held that the plaintiffs' failure-to-warn claims, in the two cases before it, were impliedly pre-empted by the FDA's actions "taken in accordance with its authority" in approving labeling for these drugs and then "clearly and publicly" rejecting the need for the additional warning argued for by the plaintiffs - that the drugs were associated with an increased risk of suicidality in adults. The Circuit found that the plaintiffs' claims represented an attempt to impose a standard of care on the defendants in regard to the labeling of these drugs that would conflict with the FDA-approved standard, which was comprised not only of the FDA-approved labels but also of the FDA's "repeated" rejection of the scientific basis for the warning proposed by plaintiffs.

Not decided in Colacicco were: 1) whether conflict pre-emption would be appropriate under different facts or broader theories of pre-emption, including whether the FDA's "mere approval" of a drug label would be sufficient; 2) whether, in the absence of the FDA's express rejection of a specific warning, FDA approval would constitute only a minimum standard, and not a ceiling as well, as the FDA has argued; and 3) whether actions against generic drug manufacturers are pre-empted on the basis of their obligations under the Hatch-Waxman Amendments.

For more information, please contact Clem Trischler at (412) 263-2000 or via e-mail at CCT@PIETRAGALLO.com, Kevin E. Raphael at (215) 320-6200 or KER@PIETRAGALLO.com, Paul K. Vey at (412) 263-2000 or PKV@PIETRAGALLO.com, or Martha S. Helmreich at (412) 263-2000 or MSH@PIETRAGALLO.com. Mr. Trischler chairs the firm's Product Liability Practice Group and Mr. Raphael and Mr. Vey are co-chairs of the firm's Health Care Litigation Practice Group.

Recent Successes

Securities Fraud: Anthony J. Basinski and **Albert N. Peterlin** obtained the dismissal of the majority of counts in a federal and state securities fraud case, including all claims under 10b-5. An investor in various oil and gas wells operated by our clients – corporate and individual directors/officers – instituted the case in the U.S. District Court for the Middle District of Pennsylvania. Judge Caldwell issued a 35-page memorandum opinion in support of the order.

Grant of Allocatur: Jeanette H. Ho successfully led the briefing efforts in getting the Pennsylvania Supreme Court to grant allocatur to review an expert witness issue in a medical malpractice case tried by **Tyler J. Smith** involving a urologist treating a cancer patient. During the trial, the lower court allowed a radiation oncologist to testify that the urologist breached the standard of care in his treatment of the patient by failing to recognize that the patient's cancer had already metastasized at the time of a bone scan and in recommending a medical procedure intended to prevent the cancer from spreading beyond the prostate. The Pietragallo attorneys argued that the Medical Care Availability and Reduction of Error Act places restrictions upon where one health care professional can testify regarding the standard of care of another such professional and that, under these provisions, a radiation oncologist is not qualified to testify regarding the standard of care of a urologist. The Supreme Court has agreed to review this question.

Defamation Defense: Joseph D. Mancano and **Divya Wallace** were successful in persuading the Pennsylvania Superior Court to affirm the trial court's grant of summary judgment in favor of their client on defamation and intentional interference with prospective contractual relation claims. The appellant's complaint had alleged that the appellee/client, chairman of the board of trustees of a local college, improperly defeated the appellant's candidacy for president of the college by making defamatory statements to members of the college's board of trustees and search committee. The appellant's complaint further alleged that the board chairman interfered with appellant's potential employment as president by preventing the board of trustees and search committee from conducting a performance assessment of his qualifications. The Superior Court rejected the appellant's arguments, finding them totally without merit. The appellant had also filed a case in federal court alleging essentially the same claims. Judge Gardner, in the U.S. District Court for the Eastern District of Pennsylvania, also granted summary judgment in favor of Mr. Mancano's and Ms. Wallace's client.

Insurance Coverage and Bad Faith: Louis C. Long successfully represented the nation's leading insurer of church-related institutions in insurance coverage and bad faith claims arising out of an accident that resulted in catastrophic injuries to a twelve-year-old girl who was attending a winter retreat sponsored by her church and another church. The accident occurred when the snowmobile she was operating struck a tree at a high rate of speed. The claims came about because the insurer allegedly refused to defend and indemnify an alleged church volunteer who had been giving the plaintiff instructions about driving the snowmobile immediately prior to her accident. All claims, including the unasserted coverage and bad faith claims of other alleged church volunteers, were resolved as a result of a global mediation. The settlement contribution made by our client to the injured party was 50 percent of its maximum available coverage and no money was paid to resolve the coverage and bad faith claims.

Medical Malpractice Defense: Tyler J. Smith won a jury verdict in Allegheny County Common Pleas Court on behalf of a local hospital in a medical malpractice case. The suit alleged that the hospital's radiologists failed to detect a leak following a vertical banded gastroplasty, which caused a delay in treatment and ultimately led to the patient's death. After an eight-day trial, the jury returned its verdict after only 30 minutes of deliberation.

Pietragallo Named a 'Go-To Law Firm' For IP Law

In a survey of in-house counsels of America's largest technology companies, Pietragallo was named as a 'Go-To Law Firm' for intellectual property by Seagate Technology.

The firm had earlier been selected as a 'Go-To Law Firm' for litigation by both Northwest Airlines and W.R. Berkley Corp., and for labor and employment law by PNC Financial Services Group, Inc.

Each year, *Corporate Counsel* magazine surveys the in-house counsels at *Fortune 500* companies throughout the United States, asking which outside law firms they use and for which particular practice area. The magazine conducts a similar survey of the in-house law departments at the largest financial services companies in the country. Law firms identified by in-house counsel in the surveys are designated as a 'Go-To Law Firm'.

Pietragallo Adds Two Associates

Anthony J. Giaramita and **Joshua Siebert** have joined the Pittsburgh office of Pietragallo as associates.

Mr. Giaramita is an associate in the commercial litigation and product liability practice groups. He served as a law clerk for the Honorable John F. DiSalle of the Washington County Court of Common Pleas.

Mr. Siebert is an associate in the commercial litigation and intellectual property litigation practice groups. He served as a judicial law clerk for the Honorable Debra Todd of the Supreme Court of Pennsylvania during her transition from the Superior Court. Mr. Siebert also has served as a staff judicial law clerk for the Honorable Max Baer of the Supreme Court of Pennsylvania and as deputy chief clerk for the Honorable Justin M. Johnson of the Superior Court of Pennsylvania.

Attorneys in the News

William Pietragallo, II was appointed by the Supreme Court of Pennsylvania as vice-chair of its Disciplinary Board. The Board, created by the Court to review conduct and assure compliance by all attorneys to the Pennsylvania Rules of Conduct, is an independent agency comprised of 14 lawyers and two non-lawyers from across the state.

William Pietragallo, II (Bet-the-Company Litigation), **Mark Gordon** (Workers' Compensation Law), **Marc S. Raspanti** (Health Care Law Litigation) and **Francis E. Pipak** (Workers' Compensation Law) were selected for inclusion in the 2008 edition of *The Best Lawyers in America*.

William Pietragallo, II and **Marc S. Raspanti** were named by *Pennsylvania Super Lawyers 2008* as two of the top 100 lawyers in Pennsylvania. In addition, Mr. Pietragallo and **Mark Gordon** were selected as two of the top 50 attorneys in Pittsburgh, and Mr. Raspanti as one of the top 100 lawyers in Philadelphia. Mr. Pietragallo and Mr. Gordon were also named as leading Business Litigation practice attorneys, and Mr. Raspanti as a leading attorney in the Criminal Defense: White Collar practice. *Pennsylvania Super Lawyers* is an annual listing of outstanding lawyers who have attained a high degree of peer recognition and professional achievement.

Gaetan J. Alfano (Business Litigation), **Joseph J. Bosick** (Civil Litigation Defense), **Gayle L. Godfrey** (Personal Injury Defense), **P. Brennan Hart** (Civil Litigation Defense), **Joseph D. Mancano** (Criminal Defense: White Collar), **Francis E. Pipak** (Workers' Compensation) and **Clem C. Trischler** (Personal Injury Defense) were selected for inclusion in *Pennsylvania Super Lawyers 2008* in their respective areas of practice.

Kathryn M. Kenyon was named by the Allegheny County Bar Association as recipient of its 2008 'Outstanding Young Lawyer Award', presented to a young lawyer who best exemplifies outstanding leadership and distinguished service to the legal profession and the community at large.

Marc S. Raspanti and **Michael A. Morse** both spoke at the Health Care Compliance Association's 12th annual Compliance Institute in New Orleans. Mr. Raspanti's presentation was on "Theories of Liability and Defenses Under the False Claims Act" and Mr. Morse's on "Mandatory Reporting of Medical Errors, Near Misses, Product Defects, and Adverse Outcomes by Acute Care Hospitals."

Bryan S. Neft was elected to the Board of Governors of the Allegheny County Bar Association.

Richard F. Moroco was a featured presenter at the 2008 Great Lakes Industrial Summit in Erie, Pennsylvania, speaking on "Global Sourcing: Legal and Practical Implications of Doing Business in China."

Pamela G. Cochenour presented an "Employment Law Update" to the Butler Human Resources Association.

Andrea M. Bartko presented an overview of recent developments in case law at the Pennsylvania Bar Institute's "Day on Real Estate."

Marc S. Raspanti and **Michael A. Morse** made a presentation on "Preparing for the Fight of Your Life: Anatomy of a Healthcare Fraud Prosecution" at the Pennsylvania Bar Institute's 14th annual Health Law Institute.

Kevin E. Raphael made two presentations with Widener University School of Law Professor Roseanne Termini at the Pennsylvania Bar Institute's 14th annual Health Law Institute. The presentations were on "Product Classification Under the United States Food, Drug, and Cosmetic Act: Food, Dietary Supplement, Cosmetic, Drug, Medical Device or Combination?" and "Hot Topics in FDA Law: Compounding, Duty to Warn, Post Market Risk Issues and Future Direction."

Marc S. Raspanti presented a National Constitution Center Audio Conference on "How to Conduct a Proper Internal Investigation and Not Screw it Up."

Louis C. Long and **Mary Margaret Hill** spoke on "Managing Your Risks: Avoiding Mistakes in Securing Additional Secured Coverage" at the Insurance Club of Pittsburgh's 82nd annual I-Day Convention.

Marc S. Raspanti spoke at Hamline University School of Law on "Off-Label Marketing of Prescription Drugs and Devices."

Joseph J. Bosick lectured at the Turner Construction School for Minority and Women-Owned Businesses at Robert Morris University on several topics related to construction law and construction agreements.

Upcoming Events

- May 30, 2008, Hershey PA; **Marc S. Raspanti** will speak on "Current Trends in Fraud Prosecutions." Contact: Pennsylvania Institute of CPAs at 215-496-9272
- June 24, 2008, Erie, PA; "Northwest Industrial Resource Center: Building a China Strategy Series." **Richard F. Moroco** will speak on "Developing an Effective China Strategy and Business Plan." Contact: Claudia Garcia at 1-814-454-7191 or claudiag@nwcommission.org
- June 29-July 2, 2008, San Francisco, CA; "American Health Lawyers Association Annual Meeting & In-House Counsel Program." **Michael A. Morse** will present with the compliance officer of Trinity Health Systems on "Mandatory Reporting of Medical Errors, Adverse Events and Device Failures and State Apology Laws." Contact: AHLA at 202-833-1100

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ATTORNEYS AT LAW

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