

Health Care Law Monthly



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HEALTH CARE LAW MONTHLY welcomes your comments and opinions. Please direct all correspondence and editorial questions to: Adriana Sciortino, LexisNexis Matthew Bender, 121 Chanlon Road, New Providence, NJ 07974 (1-908-771-8662); e-mail: adriana.sciortino@lexisnexis.com. For all other questions, call 1-800-833-9844. NOTE: The information herein should not be construed as legal advice, nor utilized to resolve legal problems.

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Physician-Hospital Integration Strategies

By

*Payal Keshvani and Amber Walsh**

In our ever-changing healthcare market, with rapid changes in reimbursement and cost centers necessitating heightened efficiency and rapidly expanding managed healthcare, many physicians and hospitals are focusing on alignment with a sense of increased urgency to create mutually beneficial results for both parties. Those players who are interested in alignment believe that integration strategies will benefit physicians and hospitals by allowing them to take advantage of better reimbursement rates, decreasing the costs of delivery of healthcare by eliminating duplicative services and increasing the quality of patients' experiences. There is a wide range of alignment strategies available to hospitals and physicians and this article will discuss the most common spectrum of strategies from the least integrated to the most integrated, including medical directorships, joint ventures, and other models. In addition, this article will discuss some of the legal and business hurdles associated with each integration strategy.

Medical Directorships, Staff Leadership Positions and Call Coverage Agreements

One of the models that provides the most retained autonomy for previously private physicians is a medical directorship or staff leadership position in which a hospital or health system can engage physicians of a practice to take on a leadership role for a particular service line or department. Hospital and health systems can benefit from improving the delivery of care with closer physician oversight and involvement and increasing efficiency.

Similarly, some hospital systems will engage physicians in compensated or uncompensated call coverage agreements to ensure sufficient coverage for community patients.

Medical directorship, staff leadership and call coverage arrangements should be carefully structured to avoid violation of the Federal Anti-Kickback

Statute (42 U.S.C. § 1320a-76(b)), Stark Law (42 U.S.C. § 1395nn) and related state-level laws. To do so, they must meet an exception to the Stark Law (most commonly the Personal Services Exception (42 U.S.C. § 1395nn(e)(3))) and should ideally meet all elements of a safe harbor to the Federal Anti-Kickback Statute (most commonly the Personal Services and Management Contracts Safe Harbor (42 C.F.R. § 1001.952(d))). Although slightly different, both the exception and the safe harbor require that the physician have specifically delineated duties. In addition, the physician and the hospital or health system must ensure that the compensation received by the physician is for fair market value, in turn requiring that the physician accurately track the services he or she is providing and the hours actually worked. Such compensation can be based on an hourly, weekly or monthly fee, but typically is not tied to referrals in any direct or indirect manner due to Stark Law and other legal considerations. There are also several other elements that must be met for such arrangements in order to ensure compliance with the safe harbor and exception.

This alignment model is one that requires the least amount of integration in that the physicians continue to be employed by their original practices and continue to bill and collect for their own professional services through that practice, although certainly these arrangements occasionally do involve hospital-employed physicians as well. Despite this retained autonomy for physicians, care should be taken to protect both parties and to ensure that the expectations of all parties are met during the negotiation process. For example, although noncompetition covenants binding physicians are less common for these types of arrangements, the hospital may have legitimate expectations for certain exclusivity commitments from the physician. Likewise, although additional benefits are not common for these arrangements, the physicians may expect special training opportunities as part of their compensation for services rendered. All such points should be negotiated and fully set forth in the applicable agreements.

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Equipment and Space Leases

A similar type of integration that also allows physicians to retain significant autonomy similar to medical directorships and staff leadership positions is equipment and space leasing. Under this model, physicians can lease space and/or equipment to a hospital for fair market value rent, although a more common approach is for physicians to lease space on a hospital campus (such as in a medical office building).

Through these models, when done effectively, the physicians and hospital can benefit from the lowered costs of shared equipment and/or space while still providing for integration that is close enough to foster a collegial relationship. Moreover, it is often advantageous for the physician to be located closer to other healthcare services as the practice can benefit from increased exposure from the increased foot traffic. Patients also benefit from a one-stop shop model where the provision of all their healthcare services in one location can make the delivery of healthcare more efficient, while permitting the physicians to continue to private practice but have access to the increased patient traffic.

Leasing space from a hospital can become an obstacle if the physician practice has any interest in selling the practice to a competing healthcare provider. It is uncommon that a hospital would permit a practice to continue to operate in the leasing hospital space if owned by a competitor. The lease should address change of control of the practice to a competitor. One option for addressing this issue is to structure the agreements in a way that both permits the physician practice from selling to a competitor but grants the lessor hospital the right to terminate the lease in such circumstance. The lessor hospital may also wish to negotiate a right of first refusal or other tighter alignment with the practice in the event of practice sale.

Much like medical directorships, equipment and space leases should be carefully structured to avoid violation of the Federal Anti-Kickback Statute, Stark Law and related state-level laws. To do so, they must meet an exception to the Stark Law (most commonly the Equipment and Space Lease Exception (42 U.S.C. § 1395nn(e)(1))) and should ideally meet all elements of a safe harbor to the Federal Anti-Kickback Statute (most commonly the Space Rentals (42 C.F.R. § 1001.952(b)) and Equipment Rentals Safe

Harbors (42 C.F.R. § 1001.952(c))). At the core of both the exception and the safe harbors is the requirement that the equipment and/or space lease rental fees be for fair market value. There are also several other elements that must be met for such arrangements in order to ensure compliance.

Joint Ventures

A model that requires further integration of a hospital and physician practice is the joint venture. Under this arrangement, a physician practice, a hospital and sometimes even a management company join together to form a separate joint venture company to own and operate an ancillary business such as a dialysis center, surgery center or specialty hospital. Joint ventures can provide strong incentives for alignment between hospitals and physicians by avoiding unnecessary duplication of costs and efficient utilization of expensive equipment and space. Joint ventures are lauded by many as an opportunity for different providers in the healthcare continuum to come together to provide insight and oversight of a particular service, often yielding enhanced quality of care. Services are provided by, and billed and collected by, the joint venture (i.e. separate and apart from the physician and hospital provider numbers).

These types of arrangements permit the physicians to remain in private practice but typically involve greater integration of the physicians and hospital or health system, with commitments among the participants to each other and the venture that limits physician autonomy more than the previously discussed models. Even before documenting such arrangement, the parties involved should be careful to align the pro formas and the valuation to ensure that the purchase price for the equity in the joint venture is for fair market value compensation. In addition, the joint venture should be structured to limit liability and maximize tax advantages. Each of the governing documents, which typically include an operating agreement, and possibly a management services agreement and/or a medical director agreement, should specifically delineate each of the party's responsibilities and duties such as the governance of the joint venture. One of the common pitfalls of a joint venture is that there is a lack of confidence between the physicians and the hospital or health system leaders, and thus the

governance should ideally be structured to ensure that all parties can participate in the governance of the joint venture. Finally, the governing documents typically also include provisions to protect all parties by including redemption mechanisms, transfer restrictions on the equity, and restrictive covenants to protect the venture.

Depending on the type of joint venture at issue, and as with all models discussed in this article, the purchase of equity into the venture and ongoing operations of the entity should be carefully structured to ensure compliance with the Stark Law (when applicable due to the provision of “designated health services”), the Federal Anti-Kickback Statute and state law.

Independent Practice Association or Physician Hospital Organization

Under this integration model, physicians and hospitals partner to form independent practice associations (IPAs) or physician-hospital organizations (PHOs) for the purpose of contracting with managed care plans, and in some cases, gaining greater purchasing power for supplies and ancillary services. PHOs and IPAs have historically been created by hospitals that were interested in establishing a bond with physicians in order to offer an attractive full-service provider product to managed-care payors and vendors. Managed care organizations and vendors can then enter into one contract with the newly-formed PHO or IPA that would simultaneously arrange for hospital services, primary care services and specialty physician services.

PHOs and IPAs often have greater bargaining power with the managed care payors and vendors than a single physician practice or hospital. To be effective, the IPA or PHO is typically clinically integrated, meaning the IPA or PHO involves a full collaboration between the physicians and the hospital to provide improved care at controlled costs. The Federal Trade Commission (FTC) has historically been concerned with collective negotiations by economically separate entities and clinical integration is a mechanism for ensuring that the parties contracting as a group are functioning as a cohesive body for certain operational matters. In a 1996 policy statement, the Department of Justice and the FTC defined clinical integration as “. . . an active and ongoing program to evaluate

and modify practice patterns by the networks’ physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: 1. Establishing mechanisms to monitor and control utilization of healthcare services that are designed to control costs and ensure quality of care; 2. Selectively choosing network physicians who are likely to further these efficiency objectives; and 3. The significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.” United States Department of Justice and Federal Trade Commission, 1996 Statements of Antitrust Enforcement Policy in Healthcare, Statement 8.B.1.

Although IPAs and PHOs have not traditionally been as popular as other models, the recent changes enacted by the Affordable Care Act (ACA), signed into law in March 2010, provide incentives for smaller physician groups to adopt and make effective use of electronic health record systems, perform well in the public reporting of quality measures and develop other efficiencies. Establishing a clinically integrated IPA or PHO can help small physician groups who wish to remain private to still share technology and care-management programs and position both physicians and hospitals to take advantage of the new payment models that require hospital-physician cooperation.

In establishing an IPA or PHO, the parties must first evaluate a few key issues, including assessing whether clinical integration standards will be met by the arrangement, determining enhanced opportunities in vendor and payor contracts and determining whether the IPA or PHO would be eligible for participation. Most IPAs and PHOs are formed as new companies and the documentation for such new company would require the parties to determine the price to participate in such venture, establishing termination rights and determining whether participating physicians will be bound by restrictive covenants limiting affiliation with other hospital systems.

Clinical Co-Management

The clinical co-management model is an arrangement whereby the hospital and physicians partner to “co-manage” a defined set of services. Under this model, a hospital or health system would engage

the physicians to manage the clinical aspects of a department or service line of the hospital, including the performance of a variety of services such as medical director services, strategic planning, scheduling and staffing and human resources duties. The services provided by the managed service line or department continue to be billed and collected for the benefit of the hospital, under the hospital's provider number. Physicians who are regularly present at the hospital with unique training in the particular specialty line are typically the physicians invited to join in the co-management process to help improve the patient experience in terms of quality, efficiency and experience. In exchange for such services, the hospital typically pays the physicians in the form of fixed fee, and in some cases the compensation also includes an incentive-based fee that is triggered by meeting certain mutually agreed upon quality or performance goals. Both the fixed and variable elements of the fee are typically paid on a monthly or quarterly basis and must be fair market value.

The legal arrangement will take the form of the hospital entering into a management agreement with a management organization that is either jointly-owned or wholly-owned by a physician group to provide the management services for the inpatient and/or outpatient components of the hospital service line. Often, the management entity is a separate entity from the physicians' own private practices to enable greater flexibility for participation of physicians within the management entity.

As with all of the previous arrangements, the co-management agreement should specifically document the duties of the physicians and require the physicians to track the hours spent providing these services to ensure that the compensation provided to the physicians is for fair market value. A fair market valuation may be completed based on the size and scope of the service line and to verify the amount of the management fee. In either legal arrangement, the parties should assess start-up costs, define decision-making structure and establish committees to effectively handle all day-to-day concerns. The parties must also consider which physicians will participate in the management entity, how entrance and exit from such entity is handled and other important operational and legal issues.

In this alignment model, the physicians most commonly remain in private practice but due to the

significant time and strategic commitment to the hospital, restrictive covenants binding their ability to compete with the hospital in that particular service line are often included.

All parties involved should understand that there is increased regulatory scrutiny, particularly in any gainsharing aspects of the arrangement. In December 2012, the Office of Inspector General (OIG) issued Advisory Opinion No. 12-22 (Opinion), related to a hospital that entered into a co-management agreement with a cardiology group. The Opinion looked at the compensation under the co-management agreement that included a performance bonus based on implementing certain patient service, quality, and cost savings measures associated with procedures performed at the hospital's cardiac catheterization laboratories. The OIG found the arrangement to be appropriate even though it did not meet the Personal Services and Management Services Safe Harbor because the compensation was not considered set in advance. At the crux of its decision, the OIG relied on the fact that the services were for fair market value, the arrangement did not harm patients, the compensation did not vary with the volume of the patients, and the compensation was not intended to provide incentives for referral. The opinion serves as a good reference in the considerations when structuring a co-management agreement.

Professional Services Agreements

One of the more fully integrated models is a professional services arrangement (PSA), which is an independent contractor model in which a physician practice remains private but is engaged by the hospital to provide professional services to hospital patients. The services provided are professional in nature (as opposed to ancillary/technical/facility services) and are billed and collected for the benefit of the hospital, under the hospital's provider number. The hospital compensates the physician or practice through periodic payment (e.g., monthly or quarterly), often tied to productivity such as a work relative value unit (wRVU) basis. Under the PSA model, because the physicians remain in their separate private practice from an employment standpoint, all benefits for all physicians, such as health insurance, malpractice insurance and 401Ks, are typically provided by the practice rather than the hospital,

although some PSAs involve closer integration whereby the private practice can participate in some unique hospital benefits as well.

The PSA model can be advantageous for physicians who are reluctant to become direct employees of the hospital. The PSA model allows greater physician autonomy and avoids the perception of being a direct employee of the hospital. Moreover, it is easier to unwind a PSA back to private practice or to fully transition the PSA into full employment of the physicians, which can be attractive to many physicians.

The PSA model requires the parties to determine the level of physician commitment that is needed by the hospital, whether it be full time, part time, or limited to particular service lines based on the needs of the hospital. Although the compensation is often tied to productivity, such compensation should always be for fair market value and in such situations, a third-party valuation is highly recommended. Much like many of the less integrated models, the parties will also need to determine a tracking system and a target number of hours that would be required from the physician practice group and how such targets impact compensation and the ongoing relationship generally.

It is important that the PSA be structured to comply with the Stark Law and Federal Anti-Kickback Statute. It is critical that the PSA be formed with the intent to provide improved patient care to a section of the hospital where a need is not being fulfilled. A PSA arrangement may fit into a few Stark Law exceptions and Federal Anti-Kickback Statute safe harbors when carefully structured.

Accountable Care Organizations

Another of the more fully-integrated models is an accountable care organization (ACO), which involves sponsorship by a hospital or health system. ACOs are organizations consisting of a variety of healthcare providers, (e.g. doctors, hospitals, clinics, labs, etc.), who organize into partnerships so that they can more effectively coordinate healthcare.

ACOs have become increasingly highlighted as the ACA provided for the establishment of a Medicare pilot project for the creation of ACOs. As defined under the ACA, an ACO is an organization that:

1. is legally organized to receive and distribute shared savings;
2. has at least 5,000 Medicare beneficiaries and sufficient primary-care physicians to serve these enrollees;
3. has agreed to participate in the program for at least a three-year period;
4. collects sufficient information concerning ACO providers such that the U.S. Secretary of Health and Human Services may determine how best to assign Medicare beneficiaries to the ACO and what constitutes shared savings;
5. has a leadership and management structure that includes clinical and administrative information systems;
6. has the guidelines and information systems to (a) promote evidenced-based medicine, (b) collect and report the necessary data to evaluate quality and cost measures, and (c) coordinate care; and
7. can demonstrate it meets patient-centeredness criteria, as determined by the Secretary.

The healthcare providers in each ACO assume joint accountability for improving healthcare quality and reducing costs. The provider mix of each ACO will depend on the specific needs of the community in which it is situated, but at the core of every ACO, is the primary care provider. Primary care provides access, disease prevention, disease management and care coordination services that leverage overall cost savings for the ACO.

The ACO model employs financial incentives to collaborate on the care of a patient. Typically, the ACO receives a global payment for the services it provides to its patients. Savings are assumed and anticipated to arise from sharing electronic medical records between providers and delivering coordinated care to patients. Any savings generated would be shared with the providers on a certain predetermined formula set in advance in the ACO's organizing documents.

One of the largest risks in the ACO model is ensuring that physicians are engaged and active participants in the ACO. Ideally, physicians should be leaders in the ACO as they are critical to improving the quality of care and making the operations more effective. The parties should always discuss the role of the physicians, especially the primary care providers, and

align incentives such that the physicians remain actively engaged in the ACO.

In addition, when first establishing the ACO structure, the parties will need to discuss the community it will serve and the provider mix it will need. The ACO organization should also be structured to best take advantage of the size, network, needs and tax advantages of the ACO. The legal documents should also set forth the procedures for joint electronic records management and allocation of the global payment and all shared savings.

Finally, an ACO is essentially the consolidation of healthcare services that could trigger Anti-Kickback and Stark law and even antitrust issues, especially because of the high risk of monopolistic behavior. The Justice Department and the Federal Trade Commission have published rules for ACOs that allow a certain level of consolidation and market share for healthcare organizations. Parties establishing an ACO should pay close attention to any new guidance issued by the government and should often audit the structure to ensure compliance with the Anti-Kickback statute, Stark law and all other applicable laws.

Although this model has garnered significant attention in the past few years since adoption of the ACA, many healthcare providers are still working to determine the true viability of the ACO model for their particular geographic and specialty focus. Although the model can take a variety of forms and certainly can involve hospital-employed physicians, it most commonly involves primary care and specialist physicians who remain in private practice but who are required to make significant commitments to the ACO and sponsoring hospital, making the ACO a more integrated (less autonomous) alignment model.

Physician Employment and Practice Acquisitions

Finally, hospital-physician employment requires the full integration of a hospital and a physician practice. The employment model often results from the purchase by a hospital or one of its affiliated hospital-owned practices, of a previously private physician practice for fair market value by acquiring substantially all of the assets or equity of the selling physician practice. The hospital then owns the practice and compensates the physicians as employees of the hospital post-closing.

Physician practice acquisitions have been growing steadily in the past few years. According to the Medical Payment Advisory Committee, from 2004 to 2011, outpatient services covered by Medicare grew by more than a third, signaling a growth area for many hospitals. In addition, according to the American Hospital Association, between 2001 and 2011, the number of physicians and dentists employed by hospitals across the USA grew by more than 40 percent. The driving force behind the increase in practice acquisitions is the changing landscape for physicians and hospitals, including ACA and commercial payor emerging incentives, new reimbursement models, and a shift of healthcare services away from inpatient hospitals to outpatient settings. Physicians also face the high costs of electronic health records and operating the practice that can make hospital employment attractive.

Hospitals are also seeing the benefits of acquiring practices by providing for call and other full service coverage. The acquisition of physician practices allows some hospitals to provide more integrated care.

In negotiating the purchase agreement, the hospital will strive to structure the transaction such that the hospital is able to limit its liability for pre-existing practice liabilities. In addition, several other sale-related issues such as representations of the physician sellers, indemnification, ongoing covenants (e.g., noncompetition, nonsolicitation of staff and patients etc.), the transition process, the right to pre-closing cash and receivables and many other related points should be carefully negotiated. Typically the purchase price paid by the hospital is a flat amount, set in advance, that must be fair market value.

Each of the continuing physicians will also sign an employment agreement with the hospital, which will address salary guarantees, any productivity-based bonuses, benefits and all other aspects of the employment relationship.

As with any alignment strategy, there are certainly challenges to a hospital employment as well. For physicians considering employment, especially those who previously ran their own practice, becoming an employee of a hospital involves naturally limited ongoing autonomy. Hospitals and physicians can often find effective ways to mitigate this loss of autonomy, such as including staff

leadership positions in the employment arrangement, and appointing physicians to lead committees that focus on improving quality and costs, all in an effort to empower physicians to continue to work to reduce costs and improve care. There are a myriad of complex issues to work through with the employment model, and physicians and hospital systems considering such a model would be wise to spend significant time on the front end considering governance issues, non-physician employment integration, referral relationships and other philosophical and operational issues to ensure the pairing makes sense for long term success for both the hospital and the physicians.

Conclusion

Each of the above physician-hospital integration strategies is unique and carries with it its own risks and advantages. Physicians and hospitals should evaluate all of the alternative integration models and the impact of each on the operation of the physician's practice and the actual needs of the hospital system. Whatever the form of integration chosen, the effectiveness of the arrangement will center on the ability of the hospital and the physicians to align incentives to improve the quality of care while lowering the costs of delivery of care.

MEALEY'S CORNER

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EMERGING DRUGS & DEVICES

11-7-2013

Johnson & Johnson, 2 Units Plead Guilty, Pay \$2.2B In Criminal, Civil Penalties

Two Johnson & Johnson subsidiaries have pleaded guilty, and the parent company and two subsidiaries will pay \$2.2 billion in criminal fines, civil penalties and forfeitures in one criminal and several civil cases for off-label marketing of three drugs, for paying kickbacks to health care providers and a nationwide pharmacy and for causing false claims to be submitted to Medicare and Medicaid, the U.S. Justice Department announced today.

Johnson & Johnson also entered into a five-year corporate integrity agreement under which it will take back bonuses from current and former executives who engage in "significant misconduct," the Justice Department said.

Risperdal Criminal Case

Janssen Pharmaceuticals Inc. pleaded guilty to one count of misbranding the antipsychotic drug Risperdal. The criminal complaint, which was filed Nov. 4 in the U.S. District Court for the Eastern District of Pennsylvania, alleges that from March 3, 2002, through Dec. 31, 2003, Janssen marketed Risperdal to treat elderly dementia patients for anxiety, agitation, depression, hostility and confusion, uses for which the drug was not approved (United States of America v. Janssen Pharmaceuticals, Inc., No. 13-cr-605, E.D. Pa.).

(Risperdal criminal agreement available 28-131107-012P)

The criminal information says Janssen provided incentives for off-label sales of Risperdal by basing the bonuses of sales representatives on all sales of the drug, including off-label prescriptions.

Under its criminal plea agreement, Janssen will pay a \$334 million criminal fine and forfeit \$66 million.

Risperdal Civil Settlement

Separately, Janssen agreed to settle four False Claims Act complaints in which the federal government filed an intervention complaint on Nov. 4 (United States of America, *ex rel.* Victoria Starr v. Janssen Pharmaceutica Prod., L.P., No. 04-1529, United States of America, *ex rel.* Lynn Powell v. Janssen Pharmaceutica Prod., L.P., No. 04-5184, United States of America, *ex rel.* Camile McGowan and Judy Doetterl v. Janssen Pharmaceutica, Inc., et al., No. 05-4536, and United States of America, *ex rel.* Kurtis J. Barry v. Ortho-McNeil-Janssen Pharms., Inc., et al., No. 10-98, E.D. Pa.).

(Risperdal civil settlement available 28-131107-013P)

Under the civil settlement, Johnson & Johnson and Janssen agreed to pay \$1.27 billion. The federal government will take \$749 million, and \$524 million will be used to reimburse state Medicaid programs.

Relators Victoria Starr, Lynn Powell, Camile McGowan, Judy Doetterl and Kurtis J. Barry will share \$112 million as their statutory share of the recovery.

Elderly, Children Targeted

In its complaint, the federal government alleged that Janssen's off-label marketing of Risperdal to elderly nursing home residents, to children and to patients with mental disabilities caused false claims to be submitted to federal health care programs. It alleges that Janssen made false and misleading statements about the safety and efficacy of Risperdal and paid kickbacks to physicians to write prescriptions for off-label uses.

The government says the Food and Drug Administration "repeatedly" told Janssen that it was misleading to market Risperdal as safe and effective for the elderly. It also says Janssen and Johnson & Johnson were aware that Risperdal posed serious health risks to the elderly, such as strokes, but downplayed the risks.

When a Johnson & Johnson study showed Risperdal had a significant risk of stroke, the government says,

it combined the data with other studies to make the risk appear lower.

Diabetes Risk Downplayed

The government also alleges that Janssen knew that Risperdal carried a risk of causing diabetes but promoted it as not doing so. When a study found that Risperdal posed the same diabetes risk as other atypical antipsychotic drugs, the government says Janssen hired an outside consultant to re-analyze the study results and publish articles stating that the drug had a lower risk of diabetes.

In addition, the government alleges that from 1999 to 2005, Janssen promoted Risperdal for use in children and patients with mental disability. It says Janssen and Johnson & Johnson knew that Risperdal carried a risk of elevating prolactin, a hormone that stimulates breast development and human milk production.

The FDA also repeatedly warned Janssen against promoting Risperdal for use in children, the government says.

In addition, the government alleges that Janssen paid speaker fees to doctors to influence them to write Risperdal prescriptions. It said company sales representatives were told to tell doctors that if they wanted the speaker fees, they had to increase their Risperdal prescriptions.

Invega Civil Settlement

Janssen also agreed to resolve allegations that from 2006 to 2009, it marketed Invega, a new antipsychotic drug for off-label uses, and made misleading statements about its safety and efficacy.

Johnson & Johnson and Janssen also agreed to a civil settlement of a 2010 False Claims Act lawsuit filed in the U.S. District Court for the District of Massachusetts (United States of America, *ex rel.* Bernard Lisitza v. Pfizer Inc., et al., No. 07-10288-RGS, D. Mass.; 2011 U.S. Dist. LEXIS 50796). That case alleges that Johnson & Johnson paid kickbacks in the form of market share rebate payments, data-purchase agreements, grants and educational funding to Omnicare, a nationwide pharmacy serving nursing homes in return for Omnicare promoting Risperdal and other Johnson & Johnson drugs.

(Massachusetts settlement agreement available 28-131107-014P)

Johnson & Johnson and Janssen will pay \$149 million to resolve the Massachusetts false claims

lawsuit. The federal government will take \$132 million, and the states will take \$17 million.

Relator Bernard Lisitza will receive \$27.2 million as his statutory share of the recovery.

Natreacor Civil Settlement

Johnson & Johnson subsidiary Scios Inc. also agreed to settle a 2009 False Claims Act lawsuit alleging that Scios marketed the heart failure drug Natreacor for off-label use in non-hospital settings (United States of America, *ex rel.* Joe Strom v. Scios, Inc., et al., No. C 05-3004 CRB, N.D. Cal.; 676 F. Supp. 2d 884). Natreacor was approved to treat patients with acutely decompensated congestive heart failure who have shortness of breath while at rest or with minimal activity.

(Scios civil settlement agreement available 28-131107-015P)

The complaint alleges that Scios marketed Natreacor for use in patients with less-severe heart failure in outpatient clinics or doctors' offices. It says Scios used a small pilot study to encourage off-label use of Natreacor, sponsored a speaker program for doctors to promote the use, encouraged hospitals to set up outpatient clinics and, in some cases, defrayed the cost of doing the latter.

Johnson & Johnson and Scios will pay \$184 million to resolve the Natreacor false claims allegations.

Relator Joe Strom will receive \$28 million as his statutory share of the recovery.

Bonus Take-Back

The Justice Department said the corporate integrity agreement requires Johnson & Johnson to recoup bonuses and other long-term incentives from certain executives if they or their subordinates engaged in significant misconduct. Repayment can be sought for current or former employees.

(Corporate integrity agreement available 28-131107-016P)

In 2012, Johnson & Johnson announced it was taking a \$600 million charge against earnings and had agreed in principal to settle False Claims Act lawsuits involving Risperdal, Invega, Natreacor and Omnicare.

In a Nov. 4 press release, Johnson & Johnson said it "accepts accountability for the actions described in the misdemeanor plea" but said the civil settlements

are not an admission of liability or wrongdoing. It said it expressly denies the civil allegations.

Counsel

In the Risperdal criminal case, the government is represented by U.S. Attorney Zane D. Memeger and Assistant U.S. Attorneys Peter F. Schenck, Richard A. Lloret and Albert S. Glenn of the U.S. Attorney's Office in Philadelphia and Assistant Attorney General Stuart F. Delery and Michael S. Blume, Jill Furman, Perham Gorji and Kevin J. Larsen of the U.S. Justice Department in Washington, D.C. Johnson & Johnson and Janssen are represented in both the criminal and civil Risperdal cases by Christopher A. Wray, Mark A. Jensen and Brandt Leibe of King & Spalding in Washington, Richard L. Scheff of Montgomery, McCracken, Walker & Rhoads in Philadelphia and Theodore V. Wells Jr. of Paul, Weiss, Rifkind, Wharton & Garrison in New York.

In the Risperdal civil cases, the government is represented by Louis D. Lappen, Margaret L. Hutchinson, Mary Catherine Frye, Charlene Keller Fullmer and Meminger of the U.S. Attorney's Office in Philadelphia and Michael D. Granston, Jamie Ann Yavelberg, Jennifer L. Cihon, Edward C. Croke and Delery of the Justice Department in Washington.

Starr is represented by Michael Mustokoff of Duane Morris in Philadelphia, Stephen A. Sheller of Sheller PC in Philadelphia and Gary M. Farmer Jr. of Farmer, Jaffe, Weissing, Edwards, Fistos & Lehrman in Fort Lauderdale, Fla. Powell is represented by John Thurman of Farrell & Thurman in Skillman, N.J.

McGowan and Doetterl are represented by Daniel Oliverio of Hodgson Russ in Buffalo, N.Y. Barry is represented by Thomas W. Sheridan of Sheridan & Murray in Philadelphia.

Additional Counsel

In the Massachusetts false claims lawsuit, the government is represented by U.S. Attorney Carmen Ortiz and Assistant U.S. Attorneys Greg Shapiro and George B. Henderson of the U.S. Attorney's Office in Boston, Robert K. DeContin of the U.S. Department of Health and Human Services in Washington and Delery of the Justice Department.

Johnson & Johnson and Janssen are represented in the Massachusetts settlement by William Sarraille

of Sidley Austin in Washington and Mark D. Seltzer of Nixon Peabody in Boston.

Lisitz is represented by Michael Behn and Linda Wyetzner of Behn & Wyetzner in Evanston, Ill.

In the Scios civil case, the government is represented by U.S. Attorney Joshua B. Eaton and Assistant U.S. Attorneys Sara Winslow and Thomas R. Green of the U.S. Attorney's Office in San Francisco and Michael D. Granston, James Ann Yavelberg, Renee S. Orleans, Kimberly I. Friday and Delery of the Justice Department in Washington. Scios is represented by John M. Potter of Quinn, Emanuel, Urquhart & Sullivan in San Francisco.

Strom is represented by Marcella Auerbach of Nolan, Auerbach & White in Fort Lauderdale.

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EMERGING DRUGS & DEVICES

11-7-2013

Boston Scientific, Guidant Pay \$30M To Settle False Claims Involving Heart Devices

Boston Scientific Corp. and its Guidant subsidiaries have agreed to pay \$30 million to settle a whistleblower lawsuit alleging that between 2002 and 2005 the defendants caused the submission of false claims to Medicare for implantable cardioverter defibrillators (ICDs) that they knew were defective, the U.S. Justice Department said in an Oct. 17 press release (United States of America, *ex rel.* James Allen v. Guidant Corporation, et al., No. 22-22, D. Minn.; See 4/5/12, Page 21).

(Settlement agreement available 28-131107-002P)

The government alleges that Guidant learned as early as April 2002 that its Prizim 2 ICD contained a defect that caused an electrical arc that short-circuited the device and failed to deliver therapeutic shocks to the hearts of patients with heart arrhythmias.

As early as November 2003, Guidant knew that there was an arcing problem in its Renewal 1 and 2 ICDs, the government says.

The government alleges that Guidant took corrective action but continued to sell defective devices that were in stock. It says that when the defendants

learned about the cause of the defect, it “took steps to hide the problems from patients, doctors and the Food and Drug Administration (FDA).”

News Article Forced Recall

“Instead of disclosing the problem, Guidant issued a misleading communication to doctors regarding the nature of the defect and did not fully disclose the problem with the device to doctors and the FDA until May 2005, after first being contacted by a New York Times reporter,” the government says. “Subsequently, the company recalled the devices after a front-page article about the defects appeared in The New York Times.”

Under the settlement, parent company Boston Scientific and subsidiaries Guidant LLC and Guidant Sales LLC and Cardiac Pacemakers Inc. will settle allegations that their actions resulted in Medicare patients getting implanted with ICDs for which the government paid.

Boston Scientific bought Guidant in 2006.

\$2.25M Relator Share

In 2011, James Allen filed a False Claims Act suit in the U.S. District Court for the District of Minnesota on behalf of the United States. The federal government elected to intervene, and after motion practice, a trial was scheduled for November.

Allen will get \$2.25 million as his statutory share for bringing the claim.

In May, Judge Donovan W. Frank stayed the case. The docket indicates that settlement discussions have been taking place since at least May.

\$536M Prior Payouts

Boston Scientific and Guidant have already paid \$536 million to settle federal criminal and civil claims and product liability claims involving defective heart devices. In 2011, Guidant LLC pleaded guilty to a misdemeanor for failing to tell the FDA about product defects (See 1/20/11, Page 6).

Guidant paid \$296 million in criminal fines and forfeiture and was placed on three years’ probation.

Previously, Guidant paid \$240 million to 8,550 personal injury plaintiffs to settle civil liability claims.

Counsel

The United States is represented by Chad A. Blumentfield, Pamela Marentette and D. Gerald Wilhelm of

the U.S. Attorney’s Office in Minneapolis; Michael D. Granston, Jonathan H. Gold and Jamie Ann Yavelberg of the U.S. Justice Department in Washington; and Robert K. DeConti of the U.S. Department of Health and Human Services in Washington.

Boston Scientific and Guidant are represented by Gabriel Egli and Michael L. Koon of Shook, Hardy & Bacon in Kansas City, Mo., Rachel A. Simek of Shook Hardy in Washington and Leif T. Simonson and James L. Volling of Faegre & Benson in Minneapolis.

Allen is represented by Daniel C. Adams of Larson King in St. Paul, Minn., Jonathan H. Bard and Dennis R. McCoy of Hiscock & Barclay in Buffalo, N.Y., and James I. Myer of Myers, Quinn & Schwartz in Williamsville, N.Y.

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EMERGING DRUGS & DEVICES

11-7-2013

ObTape MDL Judge Denies New Trial For Mentor’s Remark About Withdrawal

A Georgia federal judge overseeing the Mentor ObTape multidistrict litigation on Oct. 28 denied the plaintiff’s motion for a new trial, saying the defendant’s comment in closing arguments about a lack of Food and Drug Administration action was not improper (*Irene Morey v. Mentor Worldwide LLC*, No. 4:11-CV-5065 (CDL), M.D. Ga., Columbus Div.; 2013 U.S. Dist. LEXIS 153851; See 6/20/13, Page 4). (Opinion available 28-131107-005Z)

Irene Morey was implanted with an ObTape pelvic mesh device made by Mentor Worldwide LLC and claims to have suffered injuries from the device. She sued Mentor in the U.S. District Court for the Middle District of Georgia, alleging negligent design and negligent failure to warn.

The case was the first ObTape MDL case to go to trial; in June, a jury found in favor of Mentor.

Morey appealed, arguing that during closing arguments, Mentor’s counsel told the jury that Morey presented no evidence that the FDA had concerns about the ObTape at the time of Morey’s surgery.

Judge Initially Concerned

Judge Clay D. Land said Mentor's statement came in response to closing argument by Morey's counsel that referenced a threat by the French equivalent of the FDA that Mentor had to take a device off the market.

Judge Land said Morey's counsel did not object to Mentor's reference to the FDA but said that while the jury was deliberating, the judge "expressed concern" about the statements. The judge said he was concerned that he prevented Morey from introducing evidence that Mentor withdrew ObTape after Morey's surgery.

The judge also said he was concerned that he had prevented Morey from presenting evidence about the withdrawal while allowing Mentor to argue in closing that the previous lack of withdrawal was evidence the device was not defective. He said he considered giving the jury a curative instruction but concluded that it "could create a bigger problem."

Post-verdict, Morey argued that she was prejudiced by Mentor's argument.

'Little Improper Effect'

"Upon further consideration, the Court has determined that Mentor's counsel's challenged comments in his closing argument likely had little improper effect on the jury and were arguably not clearly contrary to previous rulings by the Court," Judge Land wrote. "Counsel's comments could have been reasonably interpreted to relate to the lack of any FDA action before Morey was implanted with ObTape, a fact that was relevant for the jury's consideration."

"As the Court ruled during the trial, the fact that the FDA took no adverse action regarding ObTape between the FDA clearance date and the date of Morey's implant could be relevant on the question whether Mentor was negligent with regard to ObTape as of the date of Morey's implant," the judge continued. "And the Court admitted evidence as to the lack of FDA action during that time period. Furthermore, the Court instructed the jury that a manufacturer's duty to design products and 'provide reasonable adequate warnings must be judged according to the knowledge and advances that existed at the time the product was designed.' "

"Therefore, it was not improper for Mentor's counsel to argue that the absence of FDA action prior to Morey's implant could be considered by the jury in

determining whether Mentor exercised ordinary care based on what Mentor knew at the time Morey was implanted with its product," Judge Land said. "Counsel's vague suggestion to the jury that they had not seen anything from the FDA could have been interpreted by the jury to refer to the period prior to Morey's implant, particularly given the Court's instructions that the jury must base its decision on the evidence it heard and not on statements by counsel."

"The Court finds that Mentor's counsel's closing argument did not contain improper or inflammatory references that were 'wholly unjustified by anything in the record,' " the judge said. "The Court further finds that Mentor's counsel did not clearly violate any order of the Court in his closing argument. And the closing argument was not 'plainly unwarranted and clearly injurious.' "

No New Trial

Judge Land said Morey is not entitled to a new trial and denied her motion.

Morey is represented by Andrew L. Davick of Meshbesh & Spence in Rochester, Minn.; Anthony J. Nemo of Meshbesh & Spence in Minneapolis; Matthew N. Metz of the Metz Law Group in Seattle; and Thomas E. Pirtle of Laminack Pirtle & Martines in Houston.

Mentor is represented by Jan R. McLean of Nilan Jonson Lewis in Minneapolis, John Q. Lewis of Tucker Ellis in Cleveland and Tracy J. Van Steenburgh of Hallelan, Lewis, Nilan & Johnson in Minneapolis.

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EMERGING DRUGS & DEVICES

11-7-2013

Avandia MDL Judge Won't Dismiss RICO, Consumer Class Actions Of Unions

The Pennsylvania federal judge overseeing the Avandia multidistrict litigation on Oct. 23 denied a defense motion to dismiss the class action racketeering and consumer protection claims by three union third-party payers (*In re Avandia Marketing,*

Sales Practices and Products Liability Litigation, MDL Docket No. 1871, No. 02-md-1871, *Allies Services Division Welfare Fund v. GlaxoSmithKline*, No. 09-730, and *UFCW Local 1776, et al. v. GlaxoSmithKline*, No. 10-2475, *United Benefit Fund v. GlaxoSmithKline*, No. 10-5419, E.D. Pa.; 2013 U.S. Dist. LEXIS 152726).

(Opinion available 28-131107-024Z)

Allied Services Division Welfare Fund, United Food and Commercial Workers (UFCW) Local 1776 and United Benefit Fund separately sued GlaxoSmithKline plc (GSK) in the U.S. District Court for the Eastern District of Pennsylvania where the Avandia multidistrict litigation is located. The plaintiffs allege that GSK violated the Racketeer Influenced and Corrupt Organizations Act and various state consumer protection laws and was unjustly enriched through its marketing of Avandia.

The plaintiffs say they were injured because they paid for Avandia prescriptions for their members when it turned out that Avandia had an undisclosed risk of heart injury. The plaintiffs seek certification of a class of similarly situated third-party payers.

GSK moved to dismiss the three complaints for failure to state a claim.

Judge's Rulings

Judge Cynthia M. Rufe denied the motion to dismiss the claim of Allied Services but directed the plaintiff to provide a status report within 14 days indicating whether it wishes to withdraw the opposition motion to file a third amended complaint.

Judge Rufe denied the motion to dismiss the claims of UFCW Local 1776.

The motion to dismiss the claims of United Benefit Fund was substantially denied. Judge Rufe found that United Benefit lacks standing to assert a claim on its own behalf under the Pennsylvania Unfair Trade Practices and Consumer Protection Law and dismissed that claim.

The judge also found that United Benefit failed to state a claim on its own behalf under the consumer protection laws of any state except New York. The dismissal was without prejudice.

Finally, Judge Rufe said GSK's motion to strike class allegations is premature and denied the motion without prejudice.

Counsel

Allied Services is represented by Arnold Levin, Daniel C. Levin and Fred S. Longer of Levin, Fishbein, Sedran & Berman in Philadelphia; Douglas R. Plymale, David B. Franco and James R. Dugan of the Dugan Law Firm in New Orleans; Jonathan Shub of Seeger Weiss in Philadelphia; and Arthur Sadin of the Sadin Law Firm in Friendswood, Texas.

UFCW Local 1776 is represented by Franco, Plymale and Dugan of the Dugan Law Firm, Eric L. Young of the Young Law Group in Philadelphia and Shub of Seeger Weiss.

United Benefit Fund is represented by Halley Finkelstein Ascher of Finkelstein Thompson in Washington, D.C., Brian J. McCormick of Sheller in Philadelphia and Tracy D. Rezvani of Rezvani, Volin & Rotbert in Washington.

GSK is represented by Anthony Vales, Michael A. Snowden, Nina M. Gussack and Yvonne M. McKenzie of Pepper Hamilton in Philadelphia.

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EMERGING DRUGS & DEVICES

11-7-2013

6th Circuit Won't Review Remand Of Darvon Cases For CAFA Interpretation

A federal appeals court on Oct. 30 denied seven petitions by 15 drug defendants to review a remand of multiplaintiff cases involving the drugs Darvon, Darvocet and propoxyphene, saying applicable case law has found that such cases do not trigger federal jurisdiction under the Class Action Fairness Act (CAFA) (*In re McKesson Corporation, et al.*, No. 13-504, 6th Cir.).

(Order available 28-131107-011R)

Multiple plaintiffs sued the 15 defendants and related entities in California state courts, alleging heart injuries from the now-withdrawn pain drugs Darvon, Darvocet and propoxyphene. The defendants removed the cases to federal district courts, and they were transferred into a multidistrict litigation in the U.S. District Court for the Eastern District of Kentucky.

The plaintiffs moved to remand, and in July the court granted the motion, sending the cases back to California state courts.

Removable Mass Tort?

The defendants petitioned the Sixth Circuit U.S. Court of Appeals for review of the remand order, arguing that the cases were mass actions removable under CAFA because they involved claims for monetary relief by more than 100 persons who propose that their cases be tried jointly or that involve common questions of fact.

The defendants are McKesson Corp., Eli Lilly and Co., AAIpharma LLC, Neosan Pharmaceuticals Inc., Xanodyne Pharmaceuticals Inc., Qualitest Pharmaceuticals Inc., Vintage Pharmaceuticals LLC, Propst Distribution Inc., Brenn Distribution Inc., Generics International (US) Inc., Teva Pharmaceuticals Inc., Mylan Pharmaceuticals Inc., Coviden PLC, Mallinckrodt Inc. and Watson Pharmaceuticals Inc.

The plaintiffs opposed review.

State Consolidation Not A Class

A Sixth Circuit panel said a review would require a determination of whether the District Court correctly concluded that the actions were not rendered class actions as a result of the plaintiffs filing a petition with California courts to consolidate their cases under Section 404 of the California Code of Civil Procedure.

The Sixth Circuit panel noted that the Ninth Circuit U.S. Court of Appeals recently addressed the same issue in a case involving the same drugs and concluded that a petition for California coordinated proceedings did not propose a joint trial for propoxyphene actions and did not create a CAFA mass action (*Romo v. Teva Pharm. USA Inc.*, ___ F.3d ___, 2013 U.S. App. LEXIS 19527 [9th Cir. Aug. 30, 2013]; See 10/3/13, Page 12).

The panel said that although CAFA authorizes a discretionary appeal of remand decisions, “We decline to grant such an appeal in this case. An appeal would require the court to resolve a factual dispute that has been addressed by numerous district courts in California and by the Ninth Circuit.”

“And it does not appear that an appeal of the remand order would significantly facilitate the development of this Court’s body of law interpreting CAFA,” the panel concluded.

Panel, Counsel

The panel consisted of Circuit Judges Damon J. Keith, Alan E. Norris and Raymond M. Kethledge.

McKesson is represented by Pavan L. Rosati of Goodman Neuman Hamilton in San Francisco. Lilly is represented by Mary Nold Larimore and Kimberly C. Metzger of Ice Miller in Indianapolis and Kevin L. Murch of Ice Miller in Columbus, Ohio.

AAIpharma and Neosan are represented by John B. Nalbandian, Ryan Christian Edwards and Russell Stanfield Sayer of Taft, Stettinius & Hollister in Cincinnati. Xanodyne is represented by Michael J. Suffern and Joseph P. Thomas of Ulmer & Berne in Cincinnati and Joshua A. Klarfeld of Ulmer & Berne in Cleveland.

Qualitest, Propst, Brenn and Vintage are represented by Carolyn Taylor and Tammara N. Tukloff of Morris, Polich & Purdy in San Diego. Vintage is also represented by Mark S. Cheffo of Quinn, Emanuel, Urquhart & Sullivan in New York.

Generics is represented by Rachel B. Passaretti-Wu of Skadden Arps in New York and by Cheffo of Quinn Emanuel. Teva is represented by Elliot H. Scherker, Brigid F. Chech Samole and Jay A. Yagoda of Greenberg Traurig in Miami and Lori G. Cohen and Victoria David Lockard of Greenberg Traurig in Atlanta.

Mylan is represented by Clem C. Trischler Jr. and Bradley A. Matta of Pietragallo, Gordon, Alfano, Bosick & Raspanti of Pittsburgh. Coviden and Mallinckrodt are represented by Bryan T. Pratt of Shook, Hardy & Bacon in Kansas City, Mo.

Watson is represented by Summer H. McMillan of Baker Donelson in Knoxville, Tenn., and Sam B. Blair Jr. of Baker Donelson in Memphis, Tenn.

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EMERGING DRUGS & DEVICES

11-7-2013

Ark. Federal Court Dismisses Indian Drug Manufacturer For Lack Of Jurisdiction

An Arkansas federal judge on Oct. 28 said the court lacks personal jurisdiction over an Indian drug

company that made contaminated antibiotic for Pfizer Inc. and sold by Pfizer to two Arkansas plaintiffs who claim they were injured (Cassandra Woods, et al. v. Claris Lifesciences Limited, et al., No. 4:13-286, Royce Brinker, et al. v. Claris Lifesciences Limited, et al., No. 4:13-302, E.D. Ark., W. Div.).

(Opinion available 28-131107-006Z)

Cassandra and Paul Woods and Royce and Ted Brinker filed separate lawsuits in the Saline County, Ark., Circuit Court against Claris Lifesciences Ltd., Claris Lifesciences Inc. and Pfizer, alleging that both were injured by the antibiotic metronidazole made by Claris for sale by Pfizer. They alleged that the defendants learned that metronidazole made by Claris India and distributed by Pfizer was contaminated with mold but delayed recalling the drug.

The defendants removed the cases to the U.S. District Court for the Eastern District of Arkansas on the basis of diversity jurisdiction. Claris, an Indian drug manufacturer, moved to dismiss the complaint, arguing that none of its entities is subject to the personal jurisdiction of courts in Arkansas.

No General, Personal Jurisdiction

Judge J. Leon Holmes said that because Claris does not own or lease property in Arkansas, does not pay taxes to the state, does not have any offices, employees, assets or bank accounts in the state, does not direct or solicit sales in the state, does not send representatives to Arkansas or any surrounding states and does not design or manufacture products in Arkansas, Woods and Brinker cannot show that Claris has continuous and systematic contacts with the state. He said the District Court thus has no general jurisdiction over the Claris defendants.

Judge Holmes said that Claris' U.S. subsidiaries (Claris USA) were not a party to the agreement by Claris India to supply metronidazole to Pfizer and did not make or distribute the drug. Although Claris USA interacted with the U.S. Food and Drug Administration as the U.S. agent for Claris India, "this contact with a U.S. regulatory agency is not of a nature of quality that would support a finding of personal jurisdiction," citing case law.

Woods and Brinker submitted as an attachment to their responses a printout from the Claris USA website. Citing case law, Judge Holmes said that

information from a passive website alone "is insufficient to confer personal jurisdiction."

Recall Letters

The plaintiffs also argued that Claris USA had contacts with Arkansas when it sent letters to physicians and clinics about the metronidazole recall. Again citing case law, Judge Holmes said that such communications are not evidence of a continuous and systematic business relationship.

In addition, the judge said letters about the recall were not about distribution of the drug.

The plaintiffs also argued that Claris USA, as agency for Claris India, received complaints from U.S. drug distributors. Judge Holmes said receiving complaints is not "providing regular advice" and distributors are not customers. "Consequently, it cannot be said that Claris USA purposefully directed activities at the State of Arkansas that gave rise to, or related to, the plaintiffs' injuries."

Effect Of FDA Regulation

The plaintiffs also argued that Claris India is subject to the court's personal jurisdiction because it subjected itself to the authority of the FDA with regard to manufacturing and inspection of products to be sold in the United States. Judge Holmes said that does not mean "that it purposefully directed its product to the State of Arkansas. Only Claris India's purposeful contacts with the State of Arkansas - not the United States generally - are relevant."

Judge Holmes said two cases cited by Woods and Brinker "are not apropos here." He said Claris India put its product in the stream of commerce "toward the United States" but did not target any specific region that included Arkansas.

Although Claris marked the drug containers for purposes of manufacturer identification, Judge Holmes said Pfizer sold the metronidazole under its own label as a Pfizer product. "Claris India may have intended to serve the U.S. market, but it did not purposefully direct its product toward the State of Arkansas," he wrote.

Policy Considerations Not Enough

"Although the State of Arkansas has an interest in providing a forum for its citizens who are injured by pharmaceuticals sold here, and although this forum obviously would be convenient to them, those considerations are insufficient to establish

personal jurisdiction over Claris India,” the judge said.

Claris’s manufacturing of metronidazole sold in Arkansas by an unaffiliated third party is insufficient under the due process clause of the 14th Amendment to the U.S. Constitution to establish personal jurisdiction over Claris India, the judge said.

Pfizer remains a defendant in the cases.

Counsel

Woods and Brinker are represented by Bud Bernard Whetstone of Whetstone & Odum and James F. Swindoll of the Law Offices of James F. Swindoll, both in Little Rock, Ark.

Claris is represented by Terry M. Henry of Blank Rome in Philadelphia and Sarah E. Cullen of Munson, Rowlett, Moore & Boone in Little Rock.

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MANAGED CARE LIABILITY REPORT

11-6-2013

Government Asks High Court To Hold Petition In Birth Control Suit

The federal government on Oct. 21 asked the U.S. Supreme Court to hold a petition for a writ of certiorari in which plaintiffs are seeking to overturn the denial of their request for a preliminary injunction in their suit challenging the birth control mandate contained in the Patient Protection and Affordable Care Act (PPACA) pending the disposition of the petition for writ of certiorari the government filed in a similar case (*Conestoga Woods Specialties Corp., et al. v. Kathleen Sebelius, et al.*, No. 13-356, U.S. Sup.; See 10/2/13, Page 6).

(Appellee brief available 31-131106-034B)

Hold Petition

The government asked the court to hold the petition for a writ of certiorari in *Conestoga Woods Specialties Corp., et al. v. Kathleen Sebelius, et al.*, pending the disposition of the petition in *Hobby Lobby Stores Inc., et al. v. Kathleen Sebelius, et al.* (No. 13-354, U.S. Sup.).

The owners of the arts and craft store Hobby Lobby and the Christian Bookstore Mardel Inc. have been granted a preliminary injunction in their challenge to the birth control mandate contained in the PPACA, and the government filed a petition for a writ of certiorari with the Supreme Court challenging the decision (See related story this issue).

The petitioners in Conestoga Wood contend that the Religious Freedom Restoration Act (RFRA) allows a for-profit corporation to deny its employees the health coverage of contraceptives to which they are otherwise entitled by federal law, based on the religious objections of the controlling shareholders. The question is important and has divided the courts of appeal, but the government says its pending petition in Hobby Lobby is a better vehicle for resolving the issue.

As such, the government says the court should hold the petition in Conestoga Wood pending disposition of the Hobby Lobby petition, and, if the Hobby Lobby petition is granted, the court’s decision in the case.

The petitioners’ separate claim that the free exercise clause of the First Amendment entitles Conestoga Wood to an exemption from the contraceptive-coverage requirements does not implicate any circuit conflict and fails under *Employment Division, Department of Human Resources of Oregon v. Smith* (494 U.S. 872, 879 [1990]), so further review of petitioners’ constitutional claim is not warranted, the government says.

Injunction Denied

In Conestoga Wood, Norman Hahn, Elizabeth Hahn, Norman Lemar Hahn, Anthony H. Hahn and Kevin Hahn (collectively, the Hahns) and Conestoga Wood Specialties Corp. sued the government in the U.S. District Court for the Eastern District of Pennsylvania, alleging that the birth control mandate contained in the PPACA violates their rights to freedom of religion, speech and association as secured by the First and Fifth Amendments to the U.S. Constitution and the RFRA.

In January, the District Court denied the plaintiffs’ request for a preliminary injunction, and the Third Circuit U.S. Court of Appeals affirmed. The plaintiffs appealed the denial to the Supreme Court.

Charles W. Proctor III of Lindsay & Dixon in Chadds Ford, Pa., and Randall Luke Wenger of Independence

Law Center in Harrisburg, Pa., represent the plaintiffs. Michelle Renee Bennett of the U.S. Department of Justice in Washington represents the defendants.

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MANAGED CARE LIABILITY REPORT

11-6-2013

Suit Over IRS Regulations In Health Care Act Continues; Injunction Denied

A District of Columbia federal judge on Oct. 22 said from the bench that he would not dismiss a suit challenging an Internal Revenue Service regulation imposed under the Patient Protection and Affordable Care Act (PPACA) that extends eligibility for premium assistance subsidies to people who purchase health insurance through exchanges established by the PPACA but that he also would not issue an order enjoining the rule (Jacqueline Halbig, et al. v. Kathleen Sebelius, et al., No. 13-623, D.D.C.; 2013 U.S. Dist. LEXIS 155229; See 10/16/13, Page 6).

(Order dismissing complaint available 31-131106-014R)

Order denying preliminary injunction available 31-131106-015R)

U.S. Judge Paul L. Friedman of the District of Columbia announced the decision in court and did not issue a written opinion.

Exchanges

Judge Friedman declined to dismiss the suit filed by Virginia resident Jacqueline Halbig, West Virginia resident David Klemencic, Tennessee resident Carrie Lowery and Texas resident Sarah Rump over IRS-promulgated regulations expanding the availability of subsidies to help people purchase health care insurance through health care exchanges.

The PPACA includes provisions for the creation of state health insurance exchanges, which are mechanisms “for organizing the health insurance marketplace to help consumers and small businesses shop for coverage in a way that permits easy comparison of available plan options based on price, benefits and services, and quality.” The PPACA requires each

state to establish an exchange by Jan. 1, 2014, but also provides that if a state opts out of the exchange, the federal government will establish and operate an exchange within the state.

The PPACA encourages states to establish exchanges with a variety of incentives, chiefly the premium-assistance subsidy for state residents purchasing individual health insurance through state-established exchanges. However, no premium-assistance subsidy will be provided unless the citizen pays for the insurance through a state-established exchange.

Thirty-four states declined to establish exchanges, making the federal government responsible for establishing exchanges in those states. Under the PPACA, the consequence of the states’ decisions not to create their own exchanges is that people who buy insurance through the federal exchanges in those states are not eligible for premium-assistance subsidies.

If people in those 34 states were ineligible for subsidies, many would be unable to afford the comprehensive coverage the PPACA’s individual mandate requires them to purchase, and they would therefore be entitled to an exemption for the mandate’s penalty. If employees in the states were ineligible for subsidies, their employers also would be exempt from the PPACA’s employer mandate to sponsor certain health coverage for their employees.

Subsidies Expanded

To address this issue, the IRS promulgated regulations expanding the availability of subsidies. The IRS rule states that subsidies shall be available to anyone “enrolled in one or more qualified health plans through an Exchange” and defines “exchange” to mean “a State Exchange, a regional Exchange, subsidiary Exchange, and Federally-facilitated Exchange.” The rule means that premium-assistance subsidies are available in all states, including those states that declined to establish their own exchange.

The plaintiffs contend that because the subsidy expansion rule makes them eligible for a premium-assistance subsidy, they will be disqualified from the exemption to the individual mandate and be subject to its penalties for failure to obtain insurance. Small businesses Innovare Health Advocates, GC Restaurants, Olde England’s Lion & Rose, Olde England’s Lion & Rose at Castle Hills, Olde England’s Lion & Rose Forum, Olde England’s Lion & Rose at Sonterra, Olde England’s Lion & Rose at Westlake

and Community National Bank all have headquarters in states that chose not to establish their own insurance exchange. The businesses contend that absent the IRS rule, they would not be subject to assessable payments under the employer mandate contained in the PPACA.

Innovare says that if it were not subject to the payments, it was preparing to expand its health insurance plan to cover all full-time employees in a manner that would likely not comply with the PPACA. The Olde England companies say they do not offer health insurance to many full-time employees and do not want to offer it to them but that choice will expose them to the assessable payments under the employer mandate. Community National Bank says its directors object to certain provisions of the PPACA, such as its definition of contraceptive and abortifacient drugs as “preventative services” and would rather drop the health insurance it offers to full-time employees than comply with the provision. However, the bank says such an action would expose it to assessable payments under the employer mandate.

The individuals and small businesses sued Kathleen Sebelius, secretary of Health and Human Services; Jacob Lew, secretary of the Treasury; Steven Miller, acting commissioner of the IRS; the departments and the IRS in the U.S. District Court for the District of Columbia, seeking a declaration that the IRS regulations are unlawful. They have asserted a claim for rulemaking in violation of the Administrative Procedure Act (APA) and sought a judgment declaring that the IRS rule violates the APA and a preliminary and permanent injunction.

The plaintiffs moved for a preliminary injunction, and the defendants moved to dismiss.

Summary Judgment

Judge Friedman said he would rule on summary judgment motions before Feb. 15, when the expansion goes into effect.

Michael A. Carvin, Jacob M. Roth and Jonathan Berry of Jones Day in Washington represent the plaintiffs. Acting Assistant Attorney General Stuart F. Delery, Deputy Assistant Attorney General Ian Heath Gershengorn, U.S. Attorney Ronald C. Machen Jr., Deputy Branch Director Sheila Lieber and Senior Trial Counsel Joel McElvain, all of the

U.S. Department of Justice in Washington, represent the government.

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MANAGED CARE LIABILITY REPORT

11-6-2013

Federal Judge: Health Care Administrator Can Hire Employees To Work On Exchange

A Maryland federal judge on Oct. 29 denied a motion for a temporary restraining order sought by a health care software and information technology (IT) services company to keep a health care administrator from soliciting and hiring its employees to work on the Maryland Health Benefit Exchange (*EngagePoint Inc. v. Noridian Healthcare Solutions*, No. 13-3184, D. Md.; 2013 U.S. Dist. LEXIS 155067).

(Opinion available 31-131106-025Z)

Health Exchange Contract

The Patient Protection and Affordable Care Act (PPACA) includes provisions for the creation of state health insurance exchanges, which are mechanisms “for organizing the health insurance marketplace to help consumers and small businesses shop for coverage in a way that permits easy comparison of available plan options based on price, benefits and services, and quality.”

The PPACA requires each state to establish an exchange by Jan. 1, 2014.

Health care administrator Noridian Healthcare Services is the prime contractor responsible for building the Maryland Health Benefit Exchange. Noridian entered into a subcontract with EngagePoint Inc., a health care software and IT services company, to be the systems integrator of the Maryland Health Benefit Exchange.

As part of the subcontract agreement, the parties agreed “during the term of this Agreement and for twelve months after its expiration or termination, neither Party will, either directly or indirectly, hire by itself (or any of its affiliates) any employee of the other Party (or any of its affiliates) who was involved

in the performance of the Party's obligations under this Agreement, unless the hiring Party obtains the written consent of the other Party."

On Oct. 25, EngagePoint received notice that Noridian had terminated the subcontract agreement. EngagePoint contends that despite the contractual provision preventing the solicitation and hiring of EngagePoint employees, on Oct. 25, 2013, Noridian solicited EngagePoint employees working on the Maryland Health Benefit Exchange project to depart EngagePoint and work for Noridian.

EngagePoint sued Noridian in the Anne Arundel County Circuit Court for breach of contract, seeking injunctive and declaratory relief. Noridian removed the case to the U.S. District Court for the District of Maryland.

While pending in state court, a state court granted a temporary restraining order (TRO) that was set to expire at 9 a.m. Oct. 29 to preserve the status quo. The District Court extended the TRO until 2 p.m. Oct. 29 when it could hear arguments on whether the TRO should continue.

No-Hire Clause

The contract at issue contains a no-hire clause with the only exception to the no-hire clause being states in Section 15(K) and reading "[e]xcept as provided in Section 5(H)." In Section 5(H), EngagePoint, the subcontractor, "acknowledges that the services provided by Contractor under the Prime Contract, including the Services provided by Subcontractor under this Agreement, are vital to the State and must be continued without interruption in the event of expiration or termination of this Agreement. Upon expiration or termination, and as requested by Contractor, Subcontractor shall take all reasonable steps to facilitate continuity of services."

The exchange was to be operational by Oct. 1 to permit enrollment by Maryland residents in health insurance plans, but additional work is required to have it fully functioning by Jan. 1, 2014, Judge James K. Bredar said.

Both parties have acknowledged some difficulty working together, prompting Noridian to terminate

the contract and immediately seek to hire EngagePoint employees that had been performing the work for Noridian under the contract, Judge Bredar said.

Reasonable Step

In denying the motion for the TRO, Judge Bredar said EngagePoint is unlikely to succeed on the merits because of the Section 5(H) exception to the no-hire clause.

"Given the time constraints and public importance of having a fully functional health insurance exchange in Maryland, the only reasonable step to facilitate continuity of services is for Noridian to hire EngagePoint's employees," Judge Bredar said. "The Court accredits and finds persuasive testimony at the hearing today that it would take weeks and possibly months to sufficiently train replacement workers to adequately perform the programming and code writing duties assigned to EngagePoint employees. Mere knowledge transfer and turning over of documents are not sufficient to satisfy the promise of continuity contained within Section 5(H)."

Also, Judge Bredar held that although EngagePoint may suffer irreparable harm by the loss of valuable employees and that the balance of equities may tip in EngagePoint's favor, the public interest weighs against EngagePoint.

"While it is certainly in the public interest to uphold the integrity of contracts, that factor does not necessarily favor EngagePoint," Judge Bredar said. "The interplay of Section 5(H) and Section 15(K) are such that the vital public interest in bringing the Health Insurance Exchange online was recognized by the parties as a specific exception to the no-hire clause. The Court, therefore, concludes that EngagePoint has not met its burden to establish entitlement to a TRO."

Maggie Grace and Ralph S. Tylker of Venable in Baltimore represent EngagePoint. Ari Scott Meltzer, Daniel P. Graham and Todd A. Bromberg of Wiley Rein in Washington, D.C., represent Noridian.

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MANAGED CARE LIABILITY REPORT

11-6-2013

Providers Fail To Allege Assignments; Federal Judge Dismisses Claims For Benefits

Health care providers seeking payment for services provided to plan participants failed to allege with specificity the assignments on which they asserted derivative standing under the Employee Retirement Income Security Act, a federal judge in New Jersey ruled Oct. 24 (NJSR Surgical Center, L.L.C., et al. v. Horizon Blue Cross Blue Shield of New Jersey, Inc., et al., No. 12-753, D.N.J.; 2013 U.S. Dist. LEXIS 153630).

(Opinion available 54-131113-020Z)

Health care providers NJSR Surgical Center L.L.C., New Jersey Spine & Rehabilitation P.C. and Pompton Anesthesia Associates P.C. sued health care insurers and plan administrators New Jersey Transit Corp.

(NJT), CareFirst of Maryland Inc., Horizon Blue Cross Blue Shield of New Jersey Inc., Anthem Health Plans Inc., County of Passaic, HealthNow New York Inc., City of Jersey City and Orange-Ulster School District Health Plan.

The providers alleged that the defendants wrongfully denied or underpaid patients' claims for reimbursement and that, as assignees of their patients' rights to benefits, they have standing to pursue payment under the health insurance plans.

The providers sought compensatory damages and attorney fees from the plans that were self-insured under ERISA and sought damages for breach of contract under state law from the plans that were non-ERISA plans.

Derivative Standing

In granting CareFirst's motion to dismiss the ERISA claims under Federal Rule of Civil Procedure 12(b)(6), U.S. Judge Kevin McNulty of the District of New Jersey noted that the Third Circuit U.S. Court of Appeals "has not dictated how specifically a plaintiff must allege the existence and contents of the assignments on which its standing rests. In this District, however, the general standard for pleading derivative ERISA standing is fairly well settled: 'Plaintiffs will meet their burden of establishing

ERISA standing if their Complaint contains specific factual allegations to render plausible their claim that the Assignments they received from the Plan Participants conferred them with the right to receive the full benefits of that Plan.' "

"Here, the complaint alleges no more than that 'the Patients provided assignments of benefits to the Plaintiffs.' That conclusory allegation, ... falls short of what is required to withstand a motion to dismiss," the judge said.

Judge McNulty granted the motion to dismiss without prejudice, adding that he was not resolving whether there was an effective anti-assignment clause in the plan policies.

However, Judge McNulty denied CareFirst's motion to dismiss for failure to allege with specificity exhaustion of administrative remedies, saying that the exhaustion requirement "is ordinarily addressed with the aid of evidence adduced in discovery, typically on a motion for summary judgment." Similarly, the judge found that the issue of the futility of pursuing administrative remedies "can be a fact-intensive inquiry" and that the required showing "is most appropriately made on summary judgment."

State Law Claim

Turning to the state law breach of contract claim, Judge McNulty ruled that New Jersey Transit, as an arm of the State of New Jersey, cannot be sued in federal court because the state has not waived its sovereign immunity.

The judge stated that even if the claim could be asserted in federal court, he would decline to exercise supplemental jurisdiction over it because the legal issues in the ERISA and state claims are "distinct."

The providers are represented by David Michael Estees and Eric D. Katz of Mazie Slater Katz & Freeman in Roseland, N.J.

CareFirst is represented by Mark J. Oberstaedt and John P. Kahn of Archer & Greiner in Haddonfield, N.J. NJST is represented by Attorney General of New Jersey Jeffrey S. Chiesa and Deputy Attorney General, Division of Law, Kenneth M. Worton in Newark. City of Jersey City is represented by Zahire Desiree Estrella of City of Jersey City Law Department in Jersey City, N.J. HealthNow is represented by Brett Justin Lean of Burns White in Cherry Hill, N.J. Anthem is represented by Mark Sigmund

Lichtenstein of Crowell & Moring in New York. Horizon is represented by Evan Neadel of Becker Meisel in Livingston, N.J.

(Additional documents available: CareFirst motion to dismiss 54-131113-021B

Opposition to CareFirst motion 54-131113-022B

CareFirst reply 54-131113-023B

Sur-reply 54-131113-024B

NJST motion to dismiss 54-131113-025B

Opposition to NJST motion 54-131113-026B)

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MANAGED CARE LIABILITY REPORT

11-6-2013

**Judge: Provider Neither Competitor Not
Consumer Of Insurer; Unfair Claim Fails**

Claims that a health insurer misrepresented its power to authorize and provide coverage for treatment form the basis for a California unfair competition law (UCL) unlawful-prong claim, but because the provider is neither a consumer nor a competitor, its unfair-prong claim fails, a federal judge held Oct. 15 (Centre for Neuro Skills v. Blue Cross of California dba Anthem Blue Cross, et al., No. 1:13-CV-00743-LJO-JLT, E.D. Cal.; 2013 U.S. Dist. LEXIS 148432). (Opinion available 58-131030-028Z)

Judge Lawrence J. O'Neill said U.S. District Court for the Eastern District of California judges carry the heaviest caseload in the nation, preventing them from devoting "inordinate time and resources to individual cases."

As such, Judge O'Neill said he could not address all the arguments raised by the parties.

"The parties and counsel are encouraged to contact the offices of United States Senators Feinstein and Boxer to address this Court's inability to accommodate the parties and this action," Judge O'Neill said.

Treatment

The ruling came in a case brought by the Centre for Neuro Skills (CNS) in May 2013 against Blue Cross

of California d/b/a Anthem Blue Cross, Anthem Blue Cross Life and Health Insurance Co. (Blue Cross), Healthcomp, Santa Rosa Rancheria Tachi Palace Hotel & Casino (plan administrator) and Santa Rosa Rancheria Tachi Palace Hotel & Casino Tribal Member Health Care Plans (plan).

CNS claimed that it treated a John Doe patient under per-diem rates negotiated with Blue Cross. In April 2010, Blue Cross sent authorization for John Doe's care and formalizing the payment rate.

CNS claims that it provided care through June 22, 2010, for which it billed Blue Cross \$146,341. Blue Cross made an initial payment and then denied coverage, CNS claims. CNS claims that Healthcomp cited an alcohol provision in John Doe's coverage and that Blue Cross was not responsible for John Doe's bills. CNS appealed the denials. When Healthcomp and the plan denied the appeals, CNS filed suit alleging violation of the Employee Retirement Income Security Act of 1976, 29 U.S. Code Section 1132(a)(1)(B), federal common law and the UCL, Business and Professions Code Section 17200, et seq.

The defendants moved to dismiss.

Responsibility

Judge O'Neill said CNS adequately alleges that Blue Cross misrepresented itself as financially responsible for John Doe's treatment. By authorizing treatment and a payment schedule and actually making some payments, Blue Cross held itself out as the responsible party, Judge O'Neill said. CNS had no way of knowing that Blue Cross lacked authority or responsibility for John Doe's treatment, Judge O'Neill said.

The negligent misrepresentation claim provides an adequate basis on which to pursue a UCL unlawful-prong claim, Judge O'Neill said.

However, CNS is neither a consumer nor a competitor of Santa Rosa and, thus, lacks the ability to pursue a UCL claim for unfair conduct, Judge O'Neill said.

Judge O'Neill also found Blue Cross a proper defendant under ERISA and that the state law claims are not preempted.

However, the plan documents clearly exclude coverage for accidents while intoxicated and thus equitable estoppel bars the federal common-law claim.

Peter J. Brachman and Daron L. Tooch of Hooper, Lundy & Bookman in Los Angeles represent CNS. Cherie Leigh Desjarlais of Decker & Desjarlais in St. Ignace, Mont., represent the plan and plan administrator. Amir Shlesinger and Monica Jar-Kay Zi of Reed Smith in Los Angeles represent Blue Cross. Robert Brandon Weeks of Healthcomp in Fresno, Calif., represents Healthcomp.

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MANAGED CARE LIABILITY REPORT

11-6-2013

California Federal Judge Dismisses Claims From Denial Of Benefits Suit

A California federal judge on Oct. 30 dismissed multiple claims from a wrongful denial of health care benefits case, saying that the defendant's actions were consistent with making a benefits determination and did not qualify as extreme and outrageous conduct (Carolyn Cooper, et al. v. Triwest Healthcare Alliance Corp., No. 11-2965, S.D. Cal.; 2013 U.S. Dist. LEXIS 155822).

(Opinion available 31-131106-031Z)

Benefits Denied

Carolyn Cooper and James Cooper receive health care benefits through TRICARE, a health care program of the U.S. Department of Defense Military Health System.

The TRICARE Management Activity (TMA) manages and administers the TRICARE program and contracts with managed care support (MCS) contractors for the purposes of administering and providing health care services to TRICARE beneficiaries. Triwest Healthcare Alliance Corp. served as the MCS.

On Sept. 18, 2008, "S.C." was born to the Coopers. The Coopers contend that at birth their daughter was healthy but that on March 28, 2009, she was diagnosed with severe global cerebral atrophy, a disease affecting the brain. The cause of the disease was unknown, but her condition "required a complex

medication regimen with a need for skilled supervision to prevent possible interaction and side effects."

On June 19, 2009, Maxim Home Health Care, a TRICARE network provider, concluded that S.C.'s condition required "Skilled Nursing Supervision" after performing an "in home" evaluation. Maxim requested the services from Triwest, but Triwest denied the request on June 29, 2009.

Following the denial, the Coopers turned to Medi-Cal, which approved skilled nursing supervision for S.C. totaling 40 hours per week. The Coopers used the 40 hours while they were at work but say they were forced to care for S.C. during their "off work" hours, which meant they were required to remain awake during the night to make sure she did not aspirate and choke. Some nights, however, the Coopers said they were unable to stay awake or took turns staying up as much as possible to make sure S.C. was properly monitored.

On June 28, 2009, the Coopers requested that Triwest reconsider its decision to deny the services and provided additional support for the request. Included with the information were details that S.C. had begun to have seizures. Triwest denied the request for reconsideration.

S.C. then began undergoing episodes of aspiration pneumonia, and the Coopers were told it was of great importance that S.C. be watched during the night so that if any vomiting occurred it could be cleaned up to prevent any possible pneumonia. Each time S.C. had an episode, she became weaker, more prone to pneumonia and more resistant to antibiotics.

Wrongful Death

In July 2010, August 2010 and November 2010, various doctors treating S.C. again requested skilled nursing supervision, but the requests were denied. The Coopers contend that they were not informed what information they needed to provide in order to get the request approved.

S.C. continued to suffer episodes of aspiration pneumonia and on Aug. 9, 2011, she died, while a final appeal of the denial was pending with the TMA.

The Coopers sued Triwest in the U.S. District Court for the Southern District of California. In a second

amended complaint, the Coopers asserted causes of action for wrongful death - tortious interference with contractual relations, wrongful death - negligence, negligent infliction of emotional distress, intentional infliction of emotional distress, survival action for tortious interference with contractual relations and survival action for negligence.

Triwest moved to dismiss the claims for wrongful death - tortious interference with contractual relations, intentional infliction of emotional distress, survival action for tortious interference with contractual relations and survival action for negligence.

Multiple Levels Of Review

Judge James Lorenz dismissed the wrongful death - tortious interference with contractual relations claim, saying that the Coopers failed to adequately allege that a valid contract existed between themselves or S.C. and a third party.

The judge dismissed the intentional infliction of emotional distress claim, saying that Triwest, after multiple levels of review, ultimately rejected the claim.

“This is tantamount to denying a claim for benefits, which does not qualify as extreme and outrageous conduct, and nothing more,” Judge Lorenz said.

The judge dismissed the survival causes of action, saying that the Coopers did not seek damages recoverable under California’s survival statute, such as medical expenses or any other pecuniary loss incurred before death, but rather only sought nonrecoverable damages.

Judge Lorenz dismissed the claims without leave to amend, saying that the Coopers failed to sufficiently assert the causes of action after multiple opportunities to amend their complaint.

Mehrshad Mirkhan of The Mirkhan Law Firm in San Diego represented the Coopers. John M. LeBlanc and Sandra I. Weishart of Barger and Wolen in Los Angeles represented Triwest.

(Additional documents available: Dismissal brief 31-131106-032B

Opposition brief 31-131106-033B)

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