

Revealing the Secrets to Success: Accounting and Legal Advice is Critical for Healthcare/Pharmaceutical Firms

Highly regulated and complex, healthcare and pharmaceutical firms need to consult financial and legal experts to maintain and expand their business opportunities.

COMPILED BY PHIL SONNEMA
CONTRIBUTING EDITOR

THE TAX AND LEGAL ISSUES THAT HEALTHCARE and pharmaceutical firms face make doing business a challenge. That's why the expertise of accounting and legal firms is so critical for industry firms that want to maintain and expand their business opportunities. Here are some case studies that demonstrate how the right advice can be the key to success.

Amper, Politziner & Mattia LLP

Hospitals are being challenged financially. This situation has developed over time as a result of the current economic environment, a reduction in census, rising costs and lower managed care reimbursement. Amper, Politziner & Mattia LLP (Amper) is in a unique position to provide healthcare and turnaround services to hospitals. One example of this effort is St. Mary's Hospital (SMH) located in Passaic, New Jersey. Amper was retained in December 2008 to assist management with the effective use of Hospital Stabilization funding and evaluate the appropriate course of action to turnaround SMH financially. Amper's evaluation resulted in a recommendation to management that they consider a Chapter 11 bankruptcy filing. SMH's Board of Directors agreed with Amper's recommendation and decided to file for Chapter 11 in Federal Bankruptcy Court. SMH started its bankruptcy period on March 9, 2009 and has been cash flow positive throughout the filing period. Prior to bankruptcy, SMH had annual losses of approximately \$15 million to \$20 million per year. The turnaround effort was the result of outstanding teamwork between hospital management, Amper's Turnaround Services Group and Healthcare Services Group. Amper is currently working with SMH management to develop a plan to exit bankruptcy.

—By Allen Wilen, CPA, CFA, CIRA, Partner, Amper Bankruptcy & Turnaround Services and Michael McLafferty, CPA, MBA, CHFP, FACMPE, Partner, Amper Healthcare Services Group

Anderson Kill & Olick, P.C.

An iron law of business is that you never know where your next liability may come from. A corollary is that you never know whether your insurance company will balk

at covering that liability. The inescapable conclusion: be prepared to fight for coverage. Anderson Kill & Olick was hired as insurance coverage counsel by a company producing dietary supplements that was sued by a class of Hindus, vegans and vegetarians because one of its supplements allegedly contained trace amounts of gelatin, not listed in the ingredients. The plaintiffs claimed they were harmed because their religious beliefs or values did not allow them to ingest animal products, including gelatin. The insurance company denied coverage on grounds that the plaintiffs did not suffer *bodily* harm. Anderson Kill filed an insurance coverage suit in a New Jersey court. While the litigation was in progress, the company went into bankruptcy, due partly to other product liability issues. The bankruptcy trustee retained Anderson Kill as special insurance counsel. In response to the insurer's coverage defense, Anderson Kill attorneys pointed out that the underlying suit did allege bodily harm—e.g., “headaches, stomach aches, nausea, vertigo, and general malaise”—as well as “feelings of guilt, shame and sin.” After the underlying case settled, the insurance company also settled, agreeing to pay most defense costs.

—By Steve J. Pudell, Managing Shareholder, Anderson Kill & Olick-Newark Office

Gibbons P.C.

The Criminal Defense Department of Gibbons P.C., which is comprised of criminal defense attorneys and former Assistant United States Attorneys, has been responding on behalf of multiple pharmaceutical companies to subpoenas regarding government investigations of pharmaceutical sales practices. Our attorneys use the subpoena responses to gather intelligence from the government as to the subject matter, scope, and status of any investigation and learn what, if any, concerns the government may have as to our client's activities. In the course of providing documents, we offer increasingly specific descriptions of our client's activities with an eye toward an advantageous resolution. Our goal is to assure the governmental authorities that our client is already taking appropriate action to address concerns, including conducting its own internal investigation,

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Each decision is a building block for future success.



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beefing up its compliance systems, and, if necessary, implementing personnel actions to address the causes of any wrongdoing and to prevent recurrence. These steps often result in not only far more telescoped and less onerous (and less expensive) subpoena productions, but also in the most favorable possible outcomes including, in the last year alone, several instances of authorities declining to prosecute clients in this area.

—By Patrick C. Dunican, Jr.,
Chairman and Managing
Director, Gibbons PC.

Hunter Group, CPA, LLC

Our business valuations team has been involved in helping resolve issues of value for hospitals and medical practices. Recently, a specialty medical group was forming a joint venture with a hospital and asked for our assistance to both review the preliminary financial documents and assess whether the suggested expense and revenue allocations made sense. Since both

the hospital and the medical group were bringing equipment, talent and patients into the venture, much was on the line. After analyzing the hospital's suggested structure for the joint venture, we were able to determine that the value of the practice was greater than the value they were being credited for. We were also able to suggest a more equitable method of determining revenue sharing which both the medical practice and the hospital agreed was appropriate. Luckily, we were brought into the negotiations at an early stage, and our in-house merger and valuations experience were given a chance to help both parties arrive at a mutually beneficial compromise where everyone will profit. In this changing marketplace, professional practices require comprehensive business valuation appraisals for a wide range of reasons. Aside from joint ventures and mergers, valuations are needed for estate planning, and buy/sell agreements, as well as for determining the minority value of a practice when new partners are arriving or when retiring partners want to leave.

—By Michael A. Gould, CPA/ABV, ASA, CVA, CFF,
Director, Hunter Group CPA LLC

KMPG LLP

A global company based in New Jersey entered into a number of strategic licensing, profit sharing and distri-

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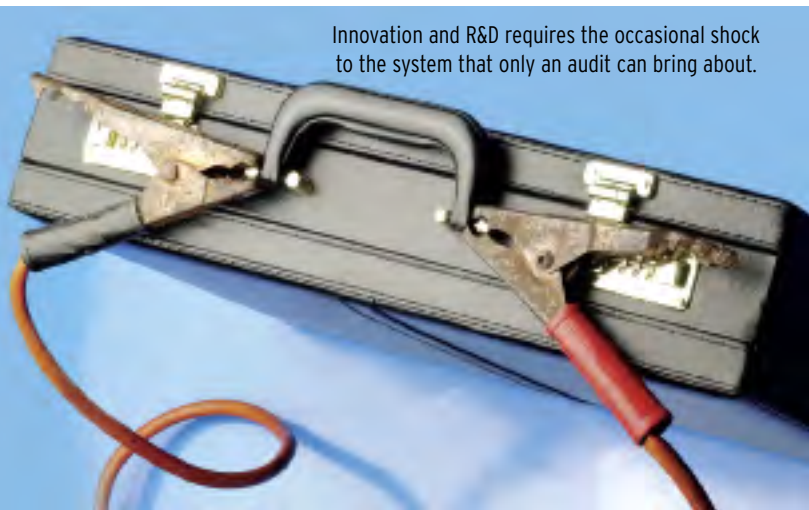
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bution services agreements with various third-party entities. As part of these agreements, the company retains the right to audit information provided by its strategic partners, including royalty amount and profitability. The company engaged KPMG LLP to assist with conducting audits of its partners' compliance with the agreements. KPMG assembled a team of professionals experienced in conducting contract compliance audits and with knowledge of the industry. In addition, KPMG applied its contract compliance services methodology

in conducting these audits. During the initial phases of the project, the engagement team deployed data analysis tools. The data analyses identified a number of potential risk areas and enabled the KPMG team to design the audit approach based on relative risks. KPMG has uncovered a number of findings, which have resulted in monetary recoveries. Under the KPMG contract compliance methodologies, each of these findings was clearly defined and accepted by the auditee. This approach facilitated the remittance of funds, while allowing the client to continue an amicable relationship with its strategic partners.

—By Ping Yu, Director, KPMG Advisory Services, Short Hills, NJ Office

Innovation and R&D requires the occasional shock to the system that only an audit can bring about.



LeClairRyan

Recently, many of our small to medium size clients have partnered with large, multi-national pharmaceutical companies in drug research and development collaborations. While these collaborations vary in structure, typically our clients provide screening, pre-clinical testing and clinical studies for identified targets and compounds through Phase II clinical studies. Following successful Phase II studies, the multi-national strategic partner completes Phase III trials, and, if successful, files for a regulatory approval and commercializes the com-

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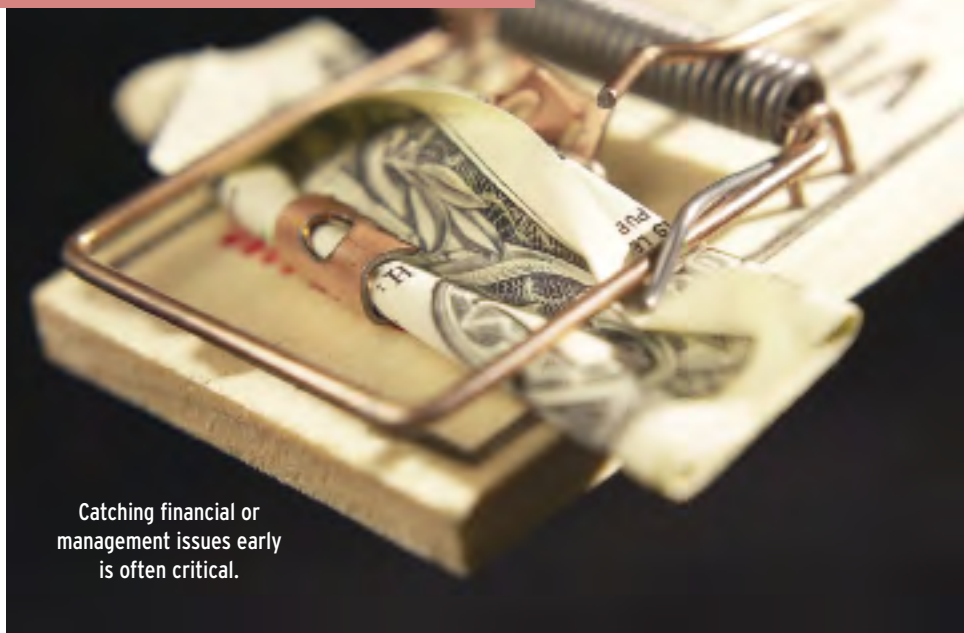
pound. Among the critical legal and business issues to be addressed as part of these collaboration agreements are the respective rights of the parties to inventions, intellectual property and resulting compounds in the event one of the parties desires to terminate the research/development. Typically, each party desires the flexibility to terminate its continued research/development efforts relating to a proposed compound for a variety of reasons, including unsatisfactory studies, difficulties encountered during research or development, increased costs, issues surrounding patent protection or prevailing marketing conditions.

We have developed a unique legal approach—a win-win scenario—by allowing clients to retain ownership and rights in development of compounds for which a multi-national partner elects to terminate further research/development, including rights in all related inventions, intellectual property and commercialization, while giving the multi-national partner the termination flexibility it desires and the added benefit of certain success-based remuneration. The addition of certain restrictive covenants also protects our client from competing efforts by the multi-national partner relating to the target and/or compound for which the partner has elected to cease further efforts under the collaboration. While multi-national partners may initially raise concerns with our approach, we have been able to secure these rights and provisions on behalf of our clients in nearly all research collaborations.

—By *John P. Reilly, Shareholder, LeClairRyan, Newark Office*

Nachman & Associates, P.C.

The healthcare sector has special needs with regard to global immigration law benefits and compliance. In one major healthcare institution, our firm continues to assist the HR department to acquire foreign national nursing and physical therapy staff to fill its ongoing needs. In another New Jersey nonprofit medical facility, our staff works closely with the medical director to identify highly qualified doctors to serve as generalists and/or specialists. We work with state government organizations to secure waivers of the two-year residency requirement under Section 212(e) of the Immigration and Nationality Act to bring doctors to rural areas of the state where they would not ordinarily go but for the opportunity to obtain a waiver to remain in the U.S. In addition, our firm assists pharmaceutical companies to acquire doctors, researchers and scientists from other countries throughout the world. For example, our staff



Catching financial or management issues early is often critical.

recently assisted one major international generic pharmaceutical firm to acquire a competitor organization in New York. The operations were combined in the New Jersey operation—which almost doubled the number of New Jersey employees. Our office assisted with the immigration-related compliance issues for the merger. We now continue to assist highly skilled researchers, scientists and doctors of that organization to stay in the United States following the acquisition.

—By *David H. Nachman, Esq., Founder and Principal, Nachman & Associates, P.C.*

Nukk-Freeman & Cerra, P.C.

Our firm represents one of the largest healthcare systems in New Jersey. This health system has a large human resources (HR) department that engaged us to do thorough, interactive and high-level training of its entire HR department on how to conduct effective investigations into allegations of workplace misconduct and/or harassment. As employment attorneys, we constantly see how investigations which are conducted properly and well-documented can bolster an employer's defense to harassment/discrimination litigation that may be filed against the employer. Specifically, New Jersey law provides a "safe harbor" to employers for harassment/discrimination complaints if the employer can prove four things: (1) it has an effective anti-harassment policy, (2) it provides anti-harassment training to all managers and other employees, (3) it conducted a thorough and effective investigation into the allegation of harassment and discrimination at issue and (4) it took appropriate remedial action as a result of the investigation. Conversely, inadequately conducted investigations can seriously harm an employer's chance of defending against harassment/discrimination litigation. Through the training, we provided the health system with a checklist and flowchart detailing the comprehensive analysis and "how-to's" of conducting workplace investi-

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gations as well as legally compliant work product and protocol which they could use thereafter when conducting workplace investigations. This proactive health system did not want to have any regrets.

—By *Katherin Nukk-Freeman, Esq., CEO and Co-Founder, Nukk-Freeman & Cerra, PC.*

PricewaterhouseCoopers

A healthcare products manufacturer headquartered in New Jersey wanted to enhance its overall efficiencies and reduce costs. Decentralized operations within the company's worldwide finance and accounting (F&A), human resources (HR), and information technology (IT) organizations had led to high administrative costs and an inability to generate global transaction reports. The company had also recently completed several acquisitions, and had the challenge of integrating disparate processes and numerous enterprise resource planning (ERP) systems. PricewaterhouseCoopers (PwC) worked with the company to develop a vision and regional model for Shared Services Centers (SSCs). The initial vision included co-locating core back office F&A and HR processes in North America, Europe, Asia and Latin America. PwC also assisted the company with a global process harmonization effort to guide design efforts for the SSC and a new standardized SAP enterprise resource planning platform. With PwC's help, the company initially launched an overseas shared service center and transitioned disparate country finance processes into a standard model. With the new SSC model, the company expects significantly lower operational costs, better data access, and more organizational control, making it easier to integrate future acquisitions.

—By *Mark Simon, Assurance Partner-U.S. Pharmaceutical and Life Sciences Industry Leader, PricewaterhouseCoopers*

Sobel & Co., LLC

In the face of mounting inquiries from its Board and scrutiny from the media, a prominent New Jersey hospital realized that its house was not in order. Patient accounts and records were not in order; funds specifically allocated from Medicare and Medicaid were commingled with other monies; and a lack of segregation of duties and hollow internal controls caused serious concern. Sobel & Co.'s Corporate Integrity Unit (CIU) was engaged to evaluate, analyze and remediate the current control environment. Sobel's CIU is co-managed by Peter Levy, a former regulatory attorney and internal control specialist. Levy noted that "the Corporate Integrity Unit provides a hospital with an integrated, seamless plan to understand its internal controls and

governance issues, while at the same time, testing for fraud vulnerability, waste, and financial abuse." During the process of assessing the current controls and risks, Sobel & Co., also uncovered a large gap in funds attributable to fraud and abuse. A new CFO is in place, and a new system of internal controls is working well.

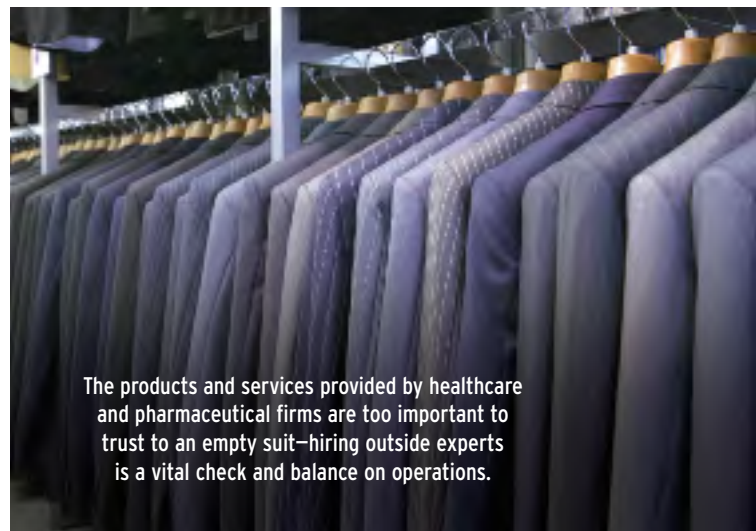
—By *Peter Levy, Principal, Sobel & Co., LLP, Head of Sobel Consulting Services LLC*

WithumSmith+Brown, PC

WS+B was approached by a New Jersey pharmaceutical company engaged in the business of research, development and commercialization of medical devices. Like most research and development companies, cash infusions are necessities to continued development. Accordingly, the company identified a public reporting shell company and completed an acquisition through a reverse merger, whereby the company's financial statements became the historical financial statements of the public reporting company as well as agreed to terms



Unraveling the problems and issues that impact the healthcare and pharmaceutical industries is a job that requires experienced engagement teams.



The products and services provided by healthcare and pharmaceutical firms are too important to trust to an empty suit—hiring outside experts is a vital check and balance on operations.

with three institutional investors in a \$5 million private placement. These transactions required the company to file Form 8-K with the Securities and Exchange Commission together with audited financial statements from their inception. Although the financial statements had been audited, the predecessor auditor would not consent to the inclusion of their audit opinion in a public filing. With time being an issue, the company engaged us to complete an audit as of the prior two years and the cumulative period to date. With our efficient and effective audit approach, we issued our audit report dated in less than six weeks and the company successfully completed its private placement. The company is currently enjoying continued success and was recently recognized in an awards program as "Company Most Likely to Succeed".

—By *John M. Mortenson, CPA, Partner, WithumSmith+Brown, PC* ■