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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

PAML, Pathology and New Opportunities

BY ANY MEASURE, MAJOR CHANGES ARE COMING to the profession of laboratory medicine. I assume that you are familiar with most of the trends, healthcare reforms, and significant reductions in lab test reimbursement that appear regularly in the headlines.

Many of these developments are unfavorable to the status quo in today's lab testing marketplace. At the same time, such changes create opportunities for nimble labs to capture new customers and increase revenue from different sources.

Thus, I am prepared to see unexpected bedfellows doing deals together in the next 12 to 24 months. One example of this is a letter of intent announced last week. **Pathology Associates Medical Laboratories** (PAML) of Spokane, Washington, will purchase a minority ownership interest in **CellNetix LLC**, the pathology laboratory company based in Seattle, Washington. PAML and CellNetix say they plan to create a jointly-owned molecular pathology esoteric testing division. CellNetix has 45 pathologists on its staff.

There are several reasons why this deal surprised laboratory professionals in Washington State. First, PAML has always had a close working relationship with **Incyte Pathology, Inc.**, also based in Spokane. Its 25 pathologists hold contracts with 25 hospitals in Spokane and across the Northwest. Incyte and CellNetix are viewed as competitors because of their size and expertise.

Second, in the Seattle-Tacoma Metropolitan area, PAML is the general partner in the **PACLAB**, a long-established regional laboratory network that includes 10 hospital laboratories. PAML has carefully remained neutral in its dealings with the different pathology groups that serve the PACLAB member hospitals. Thus, its just-announced alliance with CellNetix may be viewed in unfavorable ways by some of these pathology groups.

On the other hand, PAML and CellNetix are looking at the re-alignments taking place in healthcare today. They are willing to develop a new business strategy that they believe will allow them to jointly develop additional lab test business from sources that they could not individually win.

Further, it is significant that the goal of the two partners is specifically to work together to create a sophisticated molecular pathology esoteric testing capability. It is more evidence that specialized expertise in molecular and genetic testing will be a critical success factor for pathology laboratories. TDR

Four California Labs Sue Quest and Three Insurers

Lawsuit alleges anticompetitive practices that violate certain California and federal laws

CEO SUMMARY: Allegations of anticompetitive and monopolistic behaviors that violate state and federal laws are the basis of a private lawsuit filed by four independent clinical lab companies in California. The defendants are Quest Diagnostics Incorporated, Aetna, Blue Shield of California, and the Blue Cross Blue Shield Association. Plaintiffs claim that the defendants "conspired... to monopolize and otherwise constrain competition in the sale of routine, molecular, and specialty testing services in California."

IN CALIFORNIA, A NEWLY-FILED LAWSUIT accuses **Quest Diagnostics Incorporated, Aetna Inc., Blue Shield of California,** and the **Blue Cross and Blue Shield Association (BCBSA)** of conspiring to monopolize and restrain competition for routine, molecular, and specialty testing services in California.

Plaintiffs allege that actions taken by the defendants have resulted in an unreasonable restraint on competition in violation of federal and California law and that these actions constitute unlawful, unfair, and/or fraudulent business practices under California law. The lawsuit was filed in November.

The Plaintiffs in this lawsuit are four independent clinical laboratories. They are: **Hunter Laboratories LLC,** of Burlingame; **Pacific Breast Pathology Medical Corporation,** of Novato; **Rheumatology Diagnostics Laboratory Inc.,** of Los Angeles; and **Surgical Pathology Associates** of Los Gatos.

THE DARK REPORT believes this may be the first time such a private lawsuit has been filed against a major public laboratory company. More important, it directly challenges some of the business arrangements among public lab companies and national health insurance corporations that effectively exclude or "lock out" other laboratories from having status as contract providers for the health plans.

For this reason, although the suit was filed in California, its progress is likely to be watched by lab administrators and pathologists across the United States. In many regions of the country, certain labs may hold large market shares that involve

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the use of pricing and managed care network contracting strategies that effectively exclude competing labs in those communities.

The defendants are arguing that a large public lab company and several national health insurance corporations have engaged in behavior that violates federal anti-monopoly and restraint of trade laws—along with violation of certain California state laws. Should the plaintiffs prevail with these claims, it could establish a legal precedent that encourages similar lawsuits by smaller labs and pathology groups who consider themselves harmed by the same alleged types of monopoly actions and restraint of trade tactics described in this California lawsuit.

In response to this lawsuit, the defendants, including Quest Diagnostics, Aetna, Blue Cross Blue Shield Association, and Blue Shield of California, have denied the allegations. Each company says it will vigorously fight the charges contained within this lawsuit.

What adds interest to this case is the fact that one plaintiff is Hunter Laboratories. Its CEO, Chris Riedel, was the original whistleblower in a *qui tam* case filed in 2005. In his lawsuit, he alleged that seven California laboratory companies violated Medi-Cal laws in how they billed the program. In 2011, this case was settled by the California Attorney General and resulted in payments of more than $300 million by the defendant lab companies. *(See TDRs, April 6, 2009; February 7, 2011; and June 13, 2011.)*

Financial Resources

Having been awarded a substantial amount of money as the whistleblower in that case, Riedel has the financial resources to vigorously pursue this new lawsuit, even if it takes years to reach a trial or a settlement. Both his legal track record and his financial resources are reasons why lab industry legal experts believe this case must be taken seriously by the defendants.

It is likely that some lab administrators and pathologists will be sympathetic to the arguments of the plaintiffs. Over the years, certain business practices of large managed care plans and large lab companies have directly reduced the access that independent labs, hospital lab outreach programs, and pathology groups have to patients covered by these health plans.

On this point, the lawsuit states that, "In a threat to competition, healthcare providers and patients; defendants Blue Shield of California and Aetna have conspired with defendant Quest to monopolize and otherwise restrain competition in the sale of routine, molecular, and specialty testing services in California.

Discounted Capitated Rates

"Among other conduct, Quest systematically contracts with physician groups on a loss-leader, below-cost capitated basis," continued the lawsuit. "Quest uses the discounted capitated rates in order to lock out competition, and induce referral of Medicare and Medi-Cal pull-through business, in violation of anti-kickback statutes.

"Quest provides the capitated prices as an inducement to its customers to refer all of their lab testing business to Quest, including Medi-Cal and Medicare business, which Quest charges on a lucrative, fee-for-service basis," the suit said. "Because Quest's competitors, including plaintiffs, are unwilling to violate the law by offering such loss-leader capitated rates, Quest's capitated discounts have the effect of eliminating competition from the markets at issue in this complaint.

"Quest's loss-leader capitated contracts are specifically designed to injure competitors and destroy competition and violate the Sherman Act, California's Cartwright Act, and the explicit prohibitions of California Business and Professions Code section 17043 (California's Unfair Practices Act)," the suit alleged.

The lawsuit further claims that anti-kickback laws are violated in certain busi-

ness arrangements that Quest Diagnostics has with both Blue Cross and Aetna. On this point, the lawsuit states, "Quest uses discounted capitated rates to lock out competitors and induce the referral of Medicare and Medi-Cal pull-through business, a violation of the anti-kickback statutes.

Change To National Policy

"Quest has worked with BCBSA to change its national Blue Card policy to eliminate 'hundreds' of molecular and specialty labs," alleged the plaintiffs in the lawsuit. "Aetna and Blue Shield of California persuaded Quest to terminate the in-network status of Quest's competitors and price labs out of the market, the suit charged. Also, Aetna conspired with Quest to eliminate competition from independent regional labs.

"These actions resulted in restraint on competition in violation of federal and California law," the suit said, "and violate the Sherman Antitrust Act and California's Cartwright Act (which is similar to the Sherman Antitrust Act), the state's Unfair Competition Law, and the state's Unfair Practices Act."

Blue Card Program Changes

Another national lab industry development figures in this lawsuit. It involves significant changes to the Blue Card program now being implemented by the Blue Cross Blue Shield Association. These changes make it more difficult for many independent laboratories, hospital lab outreach programs, and pathology groups to successfully bill for lab testing services rendered to patients who travel and use their Blue Card benefits in other states. *(See TDR, July 16, 2012.)*

In their lawsuit, the plaintiffs alleged that "...Quest has worked in concert with BCBSA and member Blue plans to promote a change in the national Blue Card policy that will eliminate from the market hundreds of molecular and specialty labs operating from single locations but mar-

Four Plaintiff Labs Cite Eight Causes of Action

IN COURT PAPERS FILED IN NOVEMBER, the four plaintiffs in this case listed eight causes of action against the defendants. The causes of action describe the specific federal and California laws that are alleged to have been violated.

This lawsuit has the potential to be the first important legal test of how these laws apply in the managed care contracting practices of large clinical laboratory firms and health insurance companies:

- First Cause of Action (against all defendants): Violation of California's Cartwright Act, Cal. Bus. & Prof. Code sec §16700 et seq.
- Second Cause of Action (against all defendants): Violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code sec §17200 et seq.
- Third Cause of Action (against Quest): Violation of California's Unfair Practices Act, Cal. Bus. & Prof. Code sec §16700 et seq.
- Fourth Cause of Action (against all defendants): Intentional Interference with Prospective Economic Advantage.
- Fifth Cause of Action (against all defendants): Negligent Interference with Prospective Economic Advantage.
- Sixth Cause of Action (against all defendants): Monopolization or Attempted Monopolization, Section Two of the Sherman Act.
- Seventh Cause of Action (against all defendants): Bilateral Conspiracies to Restrain Trade and Monopolize, Section One of the Sherman Act.
- Eighth Cause of Action (against all defendants): Bilateral Conspiracies to Monopolize and Attempt to Monopolize, Section Two of the Sherman Act.

keting across the United States. These labs are the most innovative in the country, developing new tests with major impacts on patient healthcare and long-term health. The change in Blue Card policy will devastate this competitive force.

"The Blue Card Association has conspired with Quest to promote a new, exclusionary licensing agreement that requires labs to submit Blue Card members' claims to the Blue plan provider in whose region the patient is insured," the suit said. "The Blue plans must be billed by the lab which performs the test; if the patient is not insured in the region where the lab services are performed, then the plan in the patient's region will not adjudicate the claim.

Harms Competition

"Implementation of this new policy harms competition by molecular, anatomic pathology, and other specialty labs to the benefit of Quest, as physicians are likely to steer business to Quest and away from what would not be more expensive out-of-network providers under the Blue plans," the suit said.

"Furthermore, Aetna and Blue Shield of California have been successfully persuaded by Quest to terminate the in-network status of Quest's smaller competitors in exchange for Quest offering financial and other incentives. These practices have substantially foreclosed substantial distribution opportunities to large portions of the market," the suit alleged.

"Aetna has also conspired with Quest to eliminate competition within California from independent regional labs. In or about October 2012, Quest and Aetna entered into a contract whereby Aetna agreed to terminate 400 regional contracts across the United States. These terminations have increased Quest's dominance in multiple regional markets in California," the suit said.

It was known that Aetna was changing its lab network strategy with the goal of excluding many local and regional lab testing organizations. However, the extent of the lab terminations has not been previously reported.

Lab administrators and pathologists should understand that there are several distinctive features about this lawsuit. First, it does not involve either a state or local government as one of the plaintiffs.

This may be important because of past legal precedent. Historically, government attorneys proved willing to settle cases involving allegations of anti-kickback activities through the use of settlement agreements and without conducting a trial.

Because this case was filed by private parties as plaintiffs, they may prefer to see this case go to trial. This would allow the case to be judged on its merits. It would also avoid the out-of-court settlement, something that is often sealed from public view.

Second, THE DARK REPORT believes this may be the first lawsuit where laboratory plaintiffs have raised the issues of monopoly behavior and anti-competitive behavior that may be covered by the federal Sherman Act. This in itself presents a different legal threat to the four defendants.

Third, the plaintiff laboratories are also suing under multiple sections of the California state code. Again, this may be the first time that the managed care contracting practices of major payers and the national laboratories are examined for possible violations of California's statutes governing unfair competition, unfair practices, and similar anti-competitive issues.

A New Legal Challenge

At a minimum, lab administrators and pathologists should recognize that this private lawsuit filed by four independent clinical lab companies represents a new and different legal challenge to how certain lab firms and health insurance companies conduct business among themselves. TDR

—By Joseph Burns

RDX Alters Business Plan Due to Lab Market Changes

CEO cites six factors which collectively signal a time of transition for the lab testing industry

CEO SUMMARY: Executives at Regional Diagnostic Laboratories (RDX) made a splash last May when they announced the new company's plans to acquire hospital laboratory outreach programs, backed by a capital commitment of $250 million. Now, in recognition of swift changes in the lab test marketplace, RDX has pulled back and will wait for a more auspicious time to acquire hospital lab organizations. RDX says six distinct factors have combined to push the lab industry into a time of transition.

ONE OF THE NATION'S NEWEST BUYERS of clinical laboratory organizations is suspending its originally stated acquisition activities. In recent weeks, **Regional Diagnostic Laboratories, Inc.** (RDX), of Brentwood, Tennessee, adopted a strategy of watchful waiting while quietly downsizing staff.

This decision was made after seven months of conversations with hospital and health system administrators about the possibility of selling their laboratory outreach programs to RDX. These developments mirror the larger trends which are eroding the financial stability of clinical laboratories large and small across the nation.

"The environment for the laboratory testing business is particularly challenging now, and it may last for a year or more," stated Brian C. Carr, the CEO and Chairman of RDX. "A series of different headwinds are buffeting the lab industry and we believe that the industry at large is likely to undergo a significant transition.

"As an interested buyer of clinical laboratory organizations, RDX is moving to the sidelines in the near term," he explained. "We want to let these issues play out and step back into the market when the environment becomes more stable."

It was on May 1, 2012, when Carr announced the formation of Regional Diagnostic Laboratories. He had assembled a team of executives with decades of experience in the lab business and was armed with up to $250 million in capital from **Warburg Pincus**, a New York private equity firm. *(See TDR, June 25, 2012.)*

Ongoing Negotiations

As well, at that time RDX was close to completing negotiations with several major health systems to acquire their respective clinical laboratory outreach programs. RDX executives believed that at least two of these acquisition deals were likely to be consummated by summer's end.

But, according to Carr, within weeks of the announcement of RDX's formation, the clinical laboratory market began to turn. "In important respects, you can say that the laboratory testing industry has been hit by the 'perfect storm'," observed Carr. "We identified six distinct factors that caused us to change course at RDX while we let these events play out." *(See sidebar on page 9.)*

"Each factor alone would not be enough to stop RDX from pursuing the lab acquisition opportunities it saw in the marketplace," explained Carr. "However, when these six factors act in concert, it creates a substantial headwind for lab testing companies like ours that want to build market share in a financially stable manner.

"One new factor, for example, is the actual emergence of accountable care organizations (ACO) and other new integrated healthcare delivery models," noted Carr. "As of this date, no one we talked to has a clear picture of the role ACOs will play or how material they will be in healthcare delivery. Nor can they say with certainty how ACOs will reimburse clinical labs for testing services.

Possible Sale Of Labs

"We did meet with leading executives of health systems who were interested in selling their clinical lab organizations," he said. "However, the asking prices were quite high. Therefore, at this moment in time, there is a gap between the price expectations of hospital lab sellers and the prices that lab buyers are willing to pay.

"Another area of great uncertainty involves how ACOs will reimburse clinical labs for diagnostic tests," he observed. "Some administrators told us they thought fee-for-service would work for their ACOs. Other administrators thought there could be shared risk arrangements for lab providers. For us, that's a complicating variable, since most industry veterans would agree that capitation has not been favorable for clinical lab companies.

"Remember, it was back in the 1990s, when some clinical lab firms eagerly took on full-risk capitated contracts," recalled Carr. "These lab companies offered capitated rates that were below the fully-loaded cost of performing the lab tests.

"In the ensuing years, public lab companies lost millions and perhaps billions of dollars in market value," he said. "It was the rejection of HMOs by consumers and providers that eased this situation for the lab testing industry.

"Thus, the idea that ACOs might want to return to capitation as a form of reimbursement for clinical laboratory testing services is enough to create questions for us as investors," he said. "It motivates us to stand on the sidelines for a period of time and watch how this plays out with the ACO industry as it develops.

"When it comes to clinical lab testing, ACOs create uncertainty for other reasons," he added. "We know that, in preparation for the ACO model, health systems are acquiring physician practices at a much faster pace than anyone expected. Further, it is common for hospitals and health systems to want all lab testing from owned providers to stay within the new corporate entity. As this happens, it reduces the volume of lab specimens that would otherwise be available to regional independent labs and the large national labs.

"This is why, in the coming years, health systems (and ACO contracts) are likely to reconsolidate lab test volume back to labs owned by hospitals and health systems," predicted Carr. "This is the opposite of what has happened in recent decades.

"During that time, in many communities, lab test specimens flowed out of local hospital labs and into the lower cost setting of independent regional and national lab companies," he said. "That pendulum now swings in the opposite direction and favors hospital and health system labs.

Hospital Lab Outreach

"A key part of the business model for Regional Diagnostic Laboratories involves working to acquire those types of hospital lab outreach programs—we are just a bit early," said Carr. "Once these circumstances change, we firmly believe plenty of those lab organizations will once again be good acquisition targets. It's the nature of business cycles."

Carr also pointed out that managed care companies are taking active steps to

reduce the number of labs they allow in their provider networks. "This is another factor that hurts local and regional labs," he noted. "Payers are under pressure to reduce what they spend on lab testing services, in many cases due to the high growth rate they are experiencing from molecular testing.

"One high-profile example of this is how **Aetna** is reducing the number of labs in its networks across the nation," stated Carr. "Similarly, earlier this year, we understand Tennessee's Medicaid program did an exclusive statewide contract with **Quest Diagnostics Incorporated** that excluded many regional and local labs. We see aggressive Medicaid activism as a material risk factor in the near term as states move aggressively to reduce healthcare outlays.

Deep Cuts To Lab Fees

"Along with these factors are the ongoing and substantial cuts to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) and the Medicare Physician Fee Schedule (MPFS)," he added. "The recent decision by the Medicare program to drastically change reimbursement for 88305-TC is a prime example.

"The announcement about the draconian cuts to 88305-TC is unprecedented," commented Carr. "In my view, that one cut is likely to have significant impact on the anatomic pathology marketplace. Even if this decision is revised or partially reversed, it is still big, material, and unusual. It is a sign of what yet may come.

"To all of this, I would add one more factor and that is we observed what other lab industry investors were doing, particularly the ones that have already made substantial investments" concluded Carr. "It looks like they are similarly watching the lab marketplace and waiting until a more favorable environment evolves. That being said, Warburg Pincus has a long view and the ability to look across the entire diagnostic spectrum. As a result, RDX will continue to seek out quality investment opportunities during this time period."

Lab administrators and pathologists should consider the shift in strategy at Regional Diagnostic Laboratories as a significant event. It is known that RDX was very close to signing contracts to acquire at least two different hospital lab outreach organizations. That these deals fell through at this time indicates much uncertainty exists about the financial prospects of the lab testing industry. TDR

—Joseph Burns

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Six Factors in Lab Marketplace Played Role In RDX's Decision

HAVING HELD LAB ACQUISITION discussions and negotiations with a number of hospitals and health systems over the summer, Regional Diagnostic Laboratories (RDX) decided to alter its course and adopt a "wait and see attitude" going forward. Brian Carr, CEO of RDX, identified six discrete factors that contributed to this decision. They are:

1) Actions by payers such as **Aetna** and other large national health plans to narrow their networks of labs.
2) Uncertainty over how healthcare delivery would change under the Affordable Care Act.
3) The development of accountable care organizations (ACOs) and a lack of certainty as to how ACOs would pay labs for testing services.
4) More aggressive moves by state Medicaid programs to contract with fewer labs and reduce what they pay for laboratory services.
5) The dislocation of testing volume resulting from health system acquisitions of large physician practices.
6) Drastic cuts in lab test reimbursement from the federal **Centers for Medicare & Medicaid Services** (CMS).

System is used by office-based physicians

New Business Helps Reduce Pathology Specimen ID Errors

CEO SUMMARY: Prevention of diagnostic testing errors is getting more attention by both physicians and pathology labs because patients are less tolerant of potentially life-changing errors. Strand Diagnostics' Know Error system is designed to reduce or eliminate errors involving tissue specimen misidentification. In this first part of our two-part series, we provide information about the diagnostic or "prospective" use of this system by physicians. Part two addresses how pathology labs in a QA/QC or "retrospective" manner accurately identify a misidentified specimen and rectify suspected misidentification.

FIRST OF TWO PARTS

IT'S EVERY ANATOMIC PATHOLOGY LAB'S WORST NIGHTMARE. Tissue specimens from two patients get mixed up somewhere between the operating room and the pathology laboratory.

Days later, a cancer-free patient is told she has breast cancer. In the belief that the malignancy will metastasize, this woman (actually free of cancer) takes steps to have both her breasts removed. Meanwhile, a patient with cancer is mistakenly told she is cancer free, thus preventing her from getting immediate treatment for her cancer.

Such errors may become national news because of the compelling human issues involved in these situations. At the same time, consumers expect a higher standard of care and are surprised when "the system" fails individual patients in such a dramatic and life-altering fashion.

For the anatomic pathology laboratory where the mistake occurred, the consequences are significant. Besides medical malpractice liability, employees and pathologists involved in these cases of major medical errors often have emotional reactions which affect their confidence and their productivity in performing daily duties.

For many reasons, today's patient has an expectation of "zero errors," particularly for major medical mistakes that are life-changing. Yet most pathology laboratories operate with the management mindset and workflow practices developed three or four decades ago.

In recent years, companies have begun to enter the marketplace with services and solutions designed to help reduce the instances of pathology specimen misidentification or contamination. At least two companies currently offer services and systems intended to improve the accuracy and reliability of specimen identification and specimen tracking. One is **Ventana Medical Systems,** which offers products marketed specifically to pathology laboratories that are designed to eliminate errors.

The second company is **Strand Diagnostics** of Indianapolis, Indiana. A noteworthy aspect of its "Know Error" service is that it has not yet been advertised to pathology laboratories. Rather, Strand's marketing campaign targets office-based physicians who perform biopsies and send the tissues to anatomic pathology labs for evaluation.

➤ Problems of Misidentification

"The Know Error system addresses a significant problem with the diagnostic testing cycle for cancer—undetected sample contaminations and misidentifications," stated C. Michael Harmon, Vice President, Marketing & Communications for Strand Diagnostics. "Samples can be misidentified or contaminated. This can occur in the surgical suite and it can happen in the pathology laboratory.

"Our system ensures that when such errors happen—as they inevitably do—no patient is harmed!" he stated. "This is how Know Error is a *prospective* system that helps to prevent errors."

What will be of interest to pathologists and their practice managers is that, since the launch of Know Error in 2009, a *retrospective* use of the system has been discovered by a growing number of pathology groups. According to Harmon, the retrospective use was unplanned and unexpected, but meets an important need for pathology labs when errors in tissue specimen identification are discovered.

"This is the QA/QC, or *retrospective,* use of our Know Error system," he said. "We regularly get calls from pathology labs that have discovered a misidentification problem or a contamination problem involving the specimens of one or more patients.

"They ask us to help them make an accurate match of the misidentified specimen to the correct patient," he continued. "We can do this with a very high level of confidence.

"In this retrospective application, use of Know Error helps prevent a patient from get-

ting a wrong diagnosis," Harmon added. "It goes without saying that the resulting benefits to both the patient and the pathology laboratory are immense. The patient gets the right diagnosis and the laboratory has prevented an error that could have resulted in patient harm and considerable expense from malpractice litigation."

Retrospective Use

The retrospective use of Know Error will be the subject of part two in THE DARK REPORT's coverage of this market development. It is important to keep in mind that the prospective use is a specific way to minimize and prevent the sample misidentification and contamination problems inherent in the diagnostic testing cycle for cancer.

"At the launch of this service in 2009, we focused our sales and marketing efforts toward office-based physicians for several reasons," he said. "First, they perform the biopsies and collect the specimens and this is the first place in the process where a misidentification or contamination can occur.

"Second, physicians who treat patients understand that errors of mislabeling and misidentification of laboratory specimens happen with regularity—even if it is a statistically low number," continued Harmon. "Knowing this basic fact, many physicians are motivated to implement a system with protocols and a 'chain of custody' that prevents one of their patients from receiving an inaccurate pathology diagnosis because of a misidentified specimen."

Use of DNA And Bar Codes

The system Strand Diagnostics developed combines DNA testing with the use of bar codes and a chain-of-custody protocol that is similar to that used in forensic testing.

"Participating physicians using the Know Error system are sent a biopsy kit to collect a buccal swab when they do a biopsy of any patient," explained Harmon. "We instruct them to send the buccal swab to us and to send the biopsy specimens to their anatomic pathology lab.

"The benefit of having the swab and the tissue go to different sites improves the control factor," he continued. "When the biopsy samples get to the lab, the lab runs its tests.

"If cancer is detected, the lab will send us some of the patient's tissue," said Harmon. "We match that tissue against the swab. If the DNA profiles of the swab and tissues do not match, we take a 'DNA timeout' to resolve the issue before the patient gets treated.

"It's important to understand that, in this context, Know Error's DNA testing is ordered *only* when a lab makes a positive cancer diagnosis," he said. "Physicians use the Know Error system to increase patient safety and diagnostic accuracy.

Prospective Use by Doctors

"Initially, we marketed this service primarily to urologists because of the relatively high rates of positive cancer specimens they handle," stated Harmon. "The national average is about 30% to 35%, which is among the highest rate of positives of all specialties.

"A growing number of radiologists and breast surgeons also regularly use our service," he added. "These specialties all tend to have more positive cancer diagnoses for the same number of biopsies, compared to other medical specialties.

"Among breast biopsies, the rate of positive results is about 18% to 25%," he noted. "The detection rate is lower but the screening rate is higher for breast cancer than it is for prostate cancer.

"By contrast, the rates of positive diagnoses for gastroenterologists and dermatologists are significantly lower," continued Harmon. "Only about 1% of skin biopsies are positive for melanoma, for example. As a result, there is not as strong a demand for our system by these medical specialties."

In this context, Harmon was clear that it is office-based physicians and ultimately patients who are Know Error's customers.

Long Island Medical Group's Research Shows How System Reduced Specimen ID Errors

HOW SUCCESSFUL IS THE KNOW ERROR SYSTEM at preventing misidentification and specimen contamination errors in a pathology laboratory? That was the question **Integrated Medical Professionals, PLLC**, of Melville, New York, sought to answer last year.

IMP is a urology practice of more than 100 physicians who practice in 50 locations throughout Long Island in New York state. It operates an in-practice histology laboratory. Last spring, the pathologists at IMP presented a poster on this topic at the **United States and Canadian Academy of Pathology's** annual meeting in Vancouver, British Columbia.

"Despite the utilization of labeling systems, the opportunity for diagnostic mistakes due to occult specimen provenance complications persists," the poster said. "Our aim is to evaluate and compare our novel system with that of our reference laboratories using the Know Error system's DNA Specimen Provenance Assignment Assay (DSPA)."

Know Error is a system developed by Strand Diagnostics in Indianapolis, Indiana, that uses bar coded test kits and DNA matching to confirm identification of surgical biopsy samples for physician practices and pathology labs.

"We compared our unique process of specimen ownership versus the process at our reference labs," the poster said. "In a nine month period, 90 urologists swabbed 6,913 patients [after a biopsy specimen had been collected]. Of those, 2,174 patients had adenocarcinoma. Although initially there were 11 cores reported as being mismatched, these were resolved with resubmission of adequate samples. Three errors occurred at IMP Pathology, and all were contamination errors.

"For comparison, eight errors occurred at IMP's reference labs, including five that contained DNA from different persons (meaning they were wrong patient errors), and three were contamination errors," the poster said.

When IMP compared the results of its IMP Pathology Laboratory Quality System to the results of the outside reference laboratories, IMP concluded that it had fewer total non-match [specimen identification] errors compared with the reference labs and that IMP had only contamination errors that were all resolved with resubmission. It had none of the most troubling errors involving misidentified patients, the poster said.

"After extensive root cause analysis, the wrong patient errors at the outside reference laboratories were determined to be due to submission of the wrong tissue for subsequent DNA analysis, a common, but potentially devastating error in anatomic pathology," the poster said. "This error is eliminated using the IMP system."

"As part of the test requisition, when the physician orders the DNA test, the patient's insurance is billed for our services," he added. "However, that physician needs the cooperation of his or her pathology laboratory when using Know Error prospectively to avoid specimen misidentification errors.

"Once a physician adopts the system, we contact that physician's pathology laboratory and explain that one of its ordering physicians is using Know Error as a proactive step to reduce errors," stated Harmon. "We explain how the system works and what the pathology laboratory needs to do to support the program. For the most part, these pathology laboratories are eager to please their customers and they see that our process is not difficult.

"We also see a wide range of specimen types, given our mix of customers," he stated. "As you would expect, specimen

referrals from urologists, radiologists, and breast surgeons run the full gamut. In this sense, each case can be unique.

"The path a tissue specimen follows from when it is collected until the report is issued involves a long series of complicated process steps," noted Harmon. "At any step, something can go wrong.

"Pathologists know that the process of collecting and evaluating a biopsy specimen to make a cancer diagnosis involves nearly 20 steps and several medical professionals working in different locations," explained Harmon. "Such a complex process executed on a large scale increases the risk of errors.

"These errors can involve patient misidentification, specimen transposition, or foreign cell contamination—all known to occur in clinical or anatomical pathology laboratories," observed Harmon. "Should these errors go undetected, they can lead to misdiagnoses and adverse patient outcomes.

"Currently, the laboratory medicine profession recognizes that there is a recurring rate of errors—even if statistically quite low—in the handling and processing of specimens," he continued. "Further it is acknowledged that these types of errors have the potential to cause patient harm if not detected and if not corrected in a timely fashion.

Matching Patient's DNA

"The contribution of Strand Diagnostics is to introduce additional steps in the protocol," he noted. "The protocol we developed—that of having a cheek swab come to us when a biopsy is performed, then testing the patient's DNA on the swab against the DNA from the cancerous biopsy tissue—provides an important guarantee to the referring physician and her or his pathology laboratory that there should never be an adverse outcome as a result of a misidentification," Harmon asserted.

"The positive consequences of preventing just one of these serious errors is that a patient's needless pain and suffering has been avoided," he said. "On top of that, both the physician and the pathology laboratory avoid the increased liability and costs that come from diagnostic misidentification errors."

Prospective & Retrospective

In its original design, Know Error was intended to be a prospective system that would serve to reduce or prevent misidentification and contamination errors involving tissue specimens. However, it did not take long before pathology laboratories were contacting Strand Diagnostics to engage the Know Error system in a retrospective manner, to support quality control/quality assurance (QC/QA) after an error with a tissue specimen had been identified.

"We regularly work with pathology groups and hospitals who, through the course of preparing the sample for analysis, suspect that a tissue specimen misidentification or contamination error has occurred," he noted. "In these situations, Know Error is used retrospectively as part of a lab's QA/QC protocol.

"One retrospective use is to properly match a misidentified tissue specimen to the correct patient before a wrong report would be issued," Harmon explained. "In this example, the mistake is caught and corrected before it caused possible patient harm.

"Another retrospective use of Know Error is after a patient got the wrong diagnosis and inappropriate treatment," he continued. "In these types of cases, the goal of the hospital and pathology laboratory is to accurately understand and match the misidentified specimens.

"We know there is interest among risk managers from large self-insured healthcare provider organizations for the work that we do," Harmon added. "Risk managers understand the positive implications of a system that reduces liability risk for pathologists and for all providers

After Confirmation of Accurate Identification of the Patient Specimen, Know Error Files Claim

THERE ARE SIMPLE WORKFLOW, BILLING, and reimbursement requirements for office-based physicians using the Know Error system designed by Strand Diagnostics to reduce errors from misidentified tissue specimens.

"Physicians using Know Error do not bill for the Know Error service," stated C. Michael Harmon, Vice President of Marketing and Communications at Strand Diagnostics. "When they harvest biopsies, they use the collection kits we provide to them.

"Our kits include the swabs and bottles for the tissue samples," he said. "After collecting the cheek swab and doing the biopsy, the doctor sends the buccal swab to us. He or she then sends the tissue specimen to the pathology laboratory according to customary practice.

"Obviously collection of the biopsy is a billable event for the surgeon because he or she is doing a biopsy as usual and getting the buccal swab," he explained. "But we are not aware of any additional fee for collecting the cheek swab from the patient."

"Next, the physician refers the biopsy to his or her pathology laboratory," he continued. "Once the lab runs the test and has a positive diagnosis for cancer, the lab does one thing different before it sends the report to the referring doctor.

"In this situation, the Know Error protocol says the lab has a standing order to send an additional sample to Strand Diagnostics," said Harmon. "The lab gets this additional sample from the original block of patient biopsy tissue that it keeps for its own sample management purposes. We are not aware of whether the laboratory can get an additional fee for sending this sample to Strand Diagnostics.

"We use this additional sample for our confirmatory testing," added Harmon. "We run the DNA Specimen Provenance Assignment (DSPA) test on the tissue sample they send us and on the cheek swab. That's how we can confirm the identity of the patient's sample.

"That DSPA test is a billable event and Know Error will bill the commercial or government insurer using existing molecular diagnostic CPT codes," he said. "Average reimbursement is about $350 per test.

"To date, there have been very few occasions where insurers declined to pay this claim," he recalled. "Should that happen, the patient is responsible for a co-pay and a deductible. We do not balance bill any patients for out-of-network disallowances.

"To summarize, there is no charge to the laboratory to be involved in this work," concluded Harmon. "All the lab does is send us a sample of the patient's tissue from storage whenever there is a positive diagnosis. Strand Diagnostics does the necessary DNA testing to confirm the accurate identification of that patient's tissue and it will file a claim for that service."

involved in handling patient biopsies. In addition to hospital and health system risk managers, pathologists also are interested in our Know Error system, even though we do not yet market to them."

How pathology laboratories are using the Know Error system retrospectively will the focus of part two of this two-part series. Strand Diagnostics reports that this demand from pathology groups was unexpected and not part of its original business plan. Currently Strand Diagnostics is involved in as many as 20 cases per month where a pathology group suspects a misidentified tissue specimen and wants to use Know Error to correctly associate that specimen with the right patient. **TDR**

—By Joseph Burns

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Pathologists Benefit from Hospital Lab Consulting

➤Pathology group in Louisiana delivers CLIA advice and more to hospital laboratories

➤➤CEO SUMMARY: Deteriorating finances at many rural hospitals and smaller community hospitals is a growing trend. It is also a new consulting opportunity for local pathologists because financially-strapped hospitals often give their labs inadequate working capital and lack the staff needed to comply fully with state and federal compliance requirements. In Shreveport, Louisiana, Delta Pathology Group, LLC, has expanded its lab consulting business to meet demand from area hospitals for help with their lab compliance.

WHEN THE FINANCES of a rural or small community hospital deteriorate, one result is that the hospital's clinical laboratory lacks the funding and resources needed to appropriately fulfill all regulatory and compliance requirements.

Because more smaller hospitals are struggling financially across the nation, a new demand for lab consulting and laboratory management services has appeared. These are often high-stakes situations, particularly if lab regulators have identified serious deficiencies and the hospital lab must take immediate corrective action or face closure.

➤Hospital Lab As Cost Center

Often, as the financial woes of a hospital increase, administrators tend to identify their clinical laboratory as a cost center. This is particularly true when the lab has no outreach program or outreach revenue. Once administrators view their hospital lab as a cost center, a downward spiral can begin and compliance or patient-safety failures may follow.

However, starving the hospital laboratory of needed funding and resources is a high-risk strategy. Failure to comply with state and federal regulations, particularly those of the Clinical Laboratory Improvement Amendments (CLIA), can result in sanctions, loss of license, or even closure of the hospital lab.

During the past year, exactly that has happened at 173-bed **Peninsula Hospital Center** in the Far Rockaway section of the Borough of Queens in New York City and at 37-bed **E.J. Noble Hospital** in Gouverneur, New York. In both cases, regulators from the **New York State Department of Health** (NYSDOH) inspected the hospitals' laboratories and issued orders to close the laboratories due to deficiencies identified during on-site inspections of the respective labs.

Revocation of its lab's CLIA license caused Peninsula Hospital to close permanently. As of this date, it remains closed. E.J. Noble Hospital did close after the NYSDOH order revoking its laboratory's license. However, within weeks, Noble

reopened after hospital administrators negotiated a lab testing agreement with another nearby hospital that was approved by state lab regulators. *(See TDRs, March 12, 2012 and October 29, 2012.)*

Further evidence of this trend can be found in Louisiana. It was last month when THE DARK REPORT profiled the hospital laboratory consulting activities at **Delta Pathology Group, LLC**, of Shreveport, Louisiana. It was 2005 when Delta's pathologists founded **Pathology Resource Network, LLC**, (PRN) to serve as a management company to hospital laboratories in Louisiana and other states. Delta's pathologists currently serve as laboratory directors in approximately 50 hospital laboratories.

Filling a Variety of Needs

Back in 2005, PRN would be an "...opportunity to offer value in a new type of relationship with hospitals," recalled Vivek K. Khare, M.D., FCAP, a Delta pathologist. "We would offer a business solution to the problems some of our hospitals were facing with their laboratories. The solutions ranged from organizing traditional delivery of professional and technical services to offering solutions for laboratory consolidation and assistance with the due diligence required to assess whether or not to outsource the clinical laboratory."

Fast forward seven years. PRN indeed provides these services. However, its fastest-growing service line today is helping hospital administrators address problems with their laboratories' regulatory compliance. Often, these requests come from hospitals that give their labs inadequate working capital and resources.

Patient Safety Issues

"Probably the most common problems faced by labs in smaller hospitals today involve patient care and patient safety issues," stated Marilyn Bullock, Chief Compliance Officer at PRN. "More specifically, there are issues related to management, transfusion services, proficiency testing (PT), and quality assurance and quality control (QA/QC). We also see technical issues, such as test and instrument validations. The staff in these labs also need education on compliance issues."

No Surprises Among Frequent CLIA Citations

IN ITS WORK WITH HOSPITAL LABORATORIES throughout Louisiana, Pathology Resource Network of Shreveport, Louisiana, identified the most significant citations issued to laboratories by CLIA officials.

- Failure to participate in proficiency testing (PT) on regulated analytes.
- Repeated failure of PT.
- Collaboration with another lab on PT results.
- Failure to document corrective action for failed quality control.
- Failure to have diplomas on testing staff, including nurses performing non-waived point-of-care testing.
- Inadequate documentation of competency.
- Inadequate monitoring of the storage temperature of all reagents and materials and ensuring all are within the expiration date.

Among the factors that contribute to laboratory non-compliance are:

- Inadequate staffing that forces the laboratory manager to the bench rather than allowing the manager to attend to managerial duties, creating a backlog or loss of required regulatory documentation.
- Inadequate financial resources to provide for improvement in instrumentation.
- Physician demand to perform more testing in-house, causing a burden on staff.
- Loss of relief staff due to increased transportation costs to rural facilities.
- Lab manager vacancies filled with an inexperienced staff member when the financial resources needed for manager training are unavailable.

"Demand for PRN's consulting services is strong," noted Linda Price, PRN's Practice Manager. "If the hospital lab is short-staffed, the senior lab staff has to do more line testing and therefore may neglect administrative functions such as those required under CLIA. If a lab gets a CLIA inspection during this time and the inspectors find deficiencies, the lab must address those deficiencies within the prescribed time frame.

"CLIA compliance can be a significant challenge for a short-staffed hospital laboratory," she added. "If a subsequent inspection finds continued violations, the lab could lose its CLIA license and therefore must cease operations. This step could result in closure of the entire hospital as well."

Lab Compliance Problems

Seeking to avoid these problems, a growing number of hospitals in Louisiana have requested PRN consultation on CLIA compliance, such as when the hospital's lab faces sanctions or a license revocation.

"One consulting project included a lab that CLIA inspectors sanctioned for inadvertently referring a proficiency test," explained Price. "The hospital lab had to cease all laboratory operations or find new management within a week. In this case, Pathology Resource Network assumed operation of the entire lab, obtained a new CLIA number, and brought the lab into operation as a new clinical lab.

"In another case, CLIA inspectors cited a lab for severe deficiencies defined as 'Immediate Jeopardy' (IJ)," she added. "The hospital developed a plan of correction for its laboratory but did not follow through on it. With the pending revocation of its CLIA certificates, this facility of the rural hospital faced closure due to its inability to provide compliant laboratory testing support for the patients.

"PRN provided a new plan of correction for deficiencies in both the lab and the hospital," continued Price. "We worked with CLIA officials to gain approval to allow a new entity, our **Omega Diagnostics Services**, to manage the lab under a new CLIA number.

"Subsequently the laboratory passed both CLIA and state follow-up inspections," she stated. "Omega obtained the necessary CLIA certificates and today PRN provides oversight management for this facility's two rural clinic labs.

Problem Prevention

"It should be noted that most of the compliance work we do is with smaller rural facilities seeking to be proactive," explained Price. "These hospitals want to prevent problems by having us do focused audits, assist with test validations, and make recommendations for documentation and process improvement.

"One out-of-state CLIA consultation we conducted involved working with a pathology group in the Northeastern United States," stated Price. "CLIA inspectors cited the laboratory for a failure in its histology lab. When the lab was in imminent danger of receiving sanctions, the lab director asked for our assistance in developing a plan of correction.

Policies And Procedures

"PRN provided the policies and procedures," she stated. "It worked with the lab staff to implement a QA plan to ensure ongoing compliance. The QA plan provided the framework for the leadership to make improvements and this laboratory was subsequently fully accredited."

Two useful insights can be found in the experience of Delta Pathology and its PRN consulting subsidiary. First, there is growing demand by both rural hospitals and smaller community hospitals for consulting help in managing their labs' regulatory and compliance needs. Second, local pathology groups can benefit by providing those consulting services. TDR

—By Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Consolidation of *in vitro* diagnostics (IVD) manufacturers continues to help industry leaders become ever bigger. When **Hologic, Inc.**, of Bedford, Massachusetts, reported its third quarter earnings last month, it reported that diagnostics is now the largest business segment at the $2.6 billion company, following its acquisition of **Gen-Probe, Inc.**, last August. For third quarter, total revenue at Hologic was $589 million, of which diagnostics comprised $253.5 million, or 43% of Hologic's total revenue. The company noted that it had seen strong growth in its ThinPrep and molecular diagnostics product lines.

ABBOTT LABS PREPARES TO SPLIT ON JANUARY 1, 2013

In just a few weeks, **Abbott Laboratories, Inc.**, will split into two companies. The goal is to separate the pharmaceuticals business from the other product lines at Abbott. There is likely to be little visible change for the clinical laboratory customers. That is because diagnostics, devices, and nutritional products will continue to be sold in the company that will retain the name Abbott Laboratories. The pharmaceuticals and medical products business will move to a new company called **AbbVie** and will use the stock symbol of ABBV.

MORE ON: *Abbott*

Rick Gonzalez, a long-time Abbott executive, will be CEO of AbbVie. Miles White, current CEO of Abbott Laboratories, will remain CEO of that company after January 1, 2013. Abbott Laboratories is one of the top five global *in vitro* diagnostics manufacturers when measured by revenue.

TRANSITIONS

• **ClearPath Diagnostics** of Syracuse, New York, announced the appointment of Jack Finn as its new CEO. Finn was formerly President and CEO of **Centrex Clinical Laboratories**, where he served for 25 years.

• David L. Smalley, Ph.D., is the new President of the Mid-South Division of **American Esoteric Laboratories** (AEL), headquartered in Memphis, Tennessee. AEL is itself a division of **Sonic Healthcare USA**. Smalley had previously been Director of the T**ennessee State Public Health Laboratory** and recently retired as a Brigadier General from a 30-year career in the U.S. Army Reserves.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 31, 2012.

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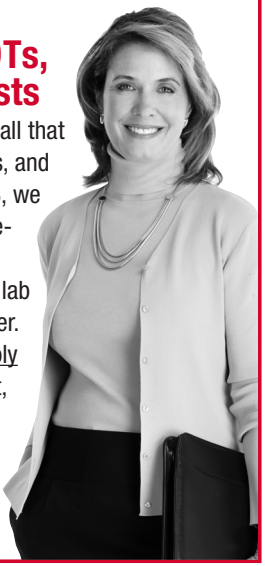

Join us for a special full-day session devoted exclusively to all that is new and important in molecular diagnostics, genetic tests, and laboratory-developed tests (LDT). On Thursday, May 2, 2013, we are assembling the leading experts in technology, reimbursement, regulatory, and compliance to give you the essential information you need to develop a test program within your lab that delivers clinical value in a financially-sustainable manner. This is practical information that you can take back and apply immediately in your lab. Seize this opportunity to hear, meet, and talk with the innovators and the leaders in the fastest-growing sector of lab testing!

For updates and program details, visit www.executivewarcollege.com

UPCOMING...

- ***Special! THE DARK REPORT's Annual List of the "Top Ten Lab Industry Stories for 2012.***
- ***Gauging How 88305-TC Cuts and Other Changes May Alter the Finances of Pathology Groups.***
- ***Newest Technologies in Clinical Laboratory Automation Designed to Integrate Informatics with Analyzers***

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