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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Pathology Across State Lines and National Borders

WE ARE SWIFTLY APPROACHING THE DAY when community hospital-based pathologists will be able to serve hospitals and physicians located across state lines with the same ease that they serve hospitals and office-based physicians in their own cities and regions.

In the same vein, at least two major academic pathology groups in the United States have announced formal agreements to provide anatomic pathology services to laboratory partners in China. In Washington State, a pathology group has a formal service relationship with a rural hospital in Alaska that uses digital pathology to support remote interoperative consults.

Digital pathology is the primary enabler of this new pathology service delivery model. Many experts predict that digital pathology will be a disruptive technology. I concur. Traditionally, pathologists have worked in close proximity to the histology laboratory. Specimens arrive at the lab, are processed by histotechnologists, then the glass slides are walked down the hallway to the waiting pathologist for his/her diagnosis.

Digital pathology disrupts this long-established service model of anatomic pathology. Whereas it has always been relatively expensive and time consuming to ship glass slides from point A to point B, there can be almost immediate access to a whole slide image via the Internet. There was also the issue that the glass slide was the primary record of the patient's case. Thus, the originating pathology laboratory needed to keep close control over those glass slides for professional, legal, and regulatory reasons.

By contrast, the digital pathology image can be permanently archived and digital copies can be accessed by authorized members of the patient's care team. As you will read on pages 10-14, **Northwest Pathology** of Bellingham, Washington, is using a digital pathology system to support interoperative consults [frozen sections] for a hospital in rural Ketchikan, Alaska. This is one of the earliest service relationships in the United States where a local pathology group in one state uses digital pathology to provide regular clinical services to a hospital client in another state—without the need to have the pathologist onsite at that location. This unique arrangement has brought benefits to both parties. This is a first-mover example in anatomic pathology that demonstrates why more and more pathology work is going to flow across state lines and even across national borders. TDR

Will Lawsuits Re-shape Current Lab Practices?

Whistleblower lawsuits have already caused far-reaching changes in the lab testing industry

CEO SUMMARY: Recent events in California, triggered by a lab whistleblower lawsuit filed in 2005 and unsealed in 2009, provide the latest example of how these lawsuits and related government enforcement actions can cause fundamental changes in the pricing and marketing practices that labs and other providers can use while staying within the laws that govern Medicare and Medicaid programs. The lab industry may want to pay attention to certain other lawsuits winding their way through state and federal courts.

IN THE PAST 25 YEARS, how many times has a whistleblower lawsuit triggered a major government enforcement action and caused an important change in the way every clinical laboratory and pathology group practice across the nation conducts business?

The answer is "More times than you think!" The question is not an idle one at this time, as events in California now demonstrate. There are trials and/or possible settlements yet to come with the other laboratory defendants in the **Hunter Laboratories LLC**/Chris Riedel whistleblower case. And it doesn't stop in California.

Both **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** have publicly stated that they have received subpoenas from as many as six other states in recent years. These subpoenas are believed to involve how medical laboratory test claims were priced to the respective state Medicaid programs. Not much attention has been given to these subpoenas and, since they remain sealed, it is unclear where, if anywhere, they might lead.

And there are other legal actions underway in various federal and state courts that involve laboratory companies. These cases sometimes center upon legal issues that, depending on how the case is resolved, can establish new legal precedents that could require a response by all laboratories in the United States. Some of these ongoing lawsuits are unsealed to the public and others are not.

For example, in this issue of THE DARK REPORT, you will learn about a lawsuit

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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winding its way in a federal court in New York. Two unions—the **Teamsters** and the **United Food and Commercial Workers** (UFCW)—have filed a nationwide class action suit against Quest Diagnostics and **Nichols Institute Diagnostics** (NID). Both defendants deny the allegations in this lawsuit and have moved to dismiss it. *(See pages 7-10.)*

Claim Of Racketeering

One of the 10 causes of action alleged by plaintiffs in this case is that the defendants violated the federal RICO (Racketeer Influenced and Corrupt Organizations Act) law because of how they manufactured, marketed, and sold certain diagnostic test kits.

If this class action lawsuit involving diagnostic laboratory test kits was to be resolved in a way that created new legal precedents, the outcome could require both clinical laboratories and *in vitro* (IVD) diagnostics manufacturers to recognize these new legal factors in how they develop, market, and/or use such diagnostic test kits.

A lack of publicity about a class action lawsuit like the one filed by the Teamsters and UFCW against Quest and NID, should not necessarily be interpreted to mean that the plaintiffs have a weak case. Take the example of the Hunter Labs/Riedel whistleblower case in California. After news coverage in 2009 of its unsealing and the related press conference by the California Attorney General, the case was given little attention and "respect" even after lab industry attorneys read the details of the plaintiff's claims. That lack of attention is no longer true.

Lab Execs Pay Attention

Across the Golden State, this Hunter Labs/Riedel whistleblower case now has the full attention of lab executives and their attorneys. That is due to the news, in May, that the California Attorney General (AG) settled with one laboratory defendant and collected almost one-quarter billion dollars as part of that settlement.

The message that was sent by this quarter-billion dollar settlement between the California AG and Quest Diagnostics (whose executives denied all the allegations of the AG in the settlement agreement) is that compliance changes are coming that will impact all laboratories operating in the state. *(See TDR, June 13, 2011.)*

Four defendant laboratories remain in the Hunter Labs/Riedel lawsuit, including LabCorp. All have denied any wrongdoing. Knowledgeable observers in California expect that, if these defendants resolve their respective cases rather than go to trial, the California Attorney General and the California **Department of Health Care Services** (DHCS) will proceed to enforce state laws pertaining to Medicaid compliance in a radically different manner than before the Hunter Labs/Riedel lawsuit was filed.

Assuming this happens in California. It will be the latest example of how a lab industry lawsuit causes the government to enforce existing state and federal laws in a different manner than before the whistleblower lawsuit was filed. But this story does not end in California.

Other State AGs Watching

There should be no doubt that the Attorneys Generals in the six other states where a whistleblower Medicaid price lawsuit is believed to be underway are closely watching the progress of the Hunter Labs/Riedel whistleblower lawsuit.

It is one reason why lab administrators and pathologists working in Florida, Georgia, Massachusetts, Michigan, Nevada, and Virginia, will want to stay current with any public information that surfaces about the progress of any whistleblower lawsuits in their respective states. These lawsuits allege that the discounted lab test prices labs give to some providers—without extending the comparable low price for those tests to the Medicaid program—violate each states' Medicaid laws.

Labscam Resulted in Several Guilty Pleas From Clinical Lab Companies During 1990s

WHEN NATIONAL HEALTH LABORATORIES and its CEO each pled guilty to a criminal felony in 1992, it was the start of a series of prosecutions by the Department of Justice (DOJ) against medical laboratory companies.

Over the next decade, several of these prosecutions similarly resulted in guilty pleas or convictions in criminal cases against laboratory testing companies.

For example, the DOJ's Operation Labscam targeted **Damon Clinical Laboratories, Inc.**, which was based in Boston, Massachusetts. It was served subpoenas in 1993 by the DOJ. In 1996, (following Damon's acquisition by **Corning Clinical Laboratories**, Inc., in 1993). Damon pled guilty to conspiracy to defraud the Medicare program. The criminal fine was $35.3 million and restitution totaled $83.7 million. Damon was permanently excluded from the Medicare program.

The interesting aspect to the Damon case is that the U.S. Attorney filed criminal charges against at least two Damon executives. Joseph E. Isola, who had been Damon's CEO, entered a nolo plea and was given three years probation.

William Thurston, formerly a Senior Vice President at Damon, entered an innocent plea and went to trial. Following a jury trial, he was convicted and was initially sentenced to imprisonment for three months and supervised release of 24 months.

In 1996, another Labscam prosecution resulted in the San Diego regional laboratory of **Allied Clinical Laboratories, Inc.**, pleading guilty to submitting a false claim to Medicare and the California Medicaid program. It was fined $5 million and excluded from participating in federal health programs. Allied had been acquired by Laboratory Corporation of America in 1994.

Back to the opening point of this intelligence briefing: on more than one occasion in the past 25 years, the prosecution and resolution of these lawsuits established legal precedents that unleashed far-reaching changes. Just as California seems to be in the midst of changing its enforcement stance relative to low prices for lab tests that it interprets violates its state law on pricing to Medi-Cal, similar changes in enforcement policies could happen in these six other states, relative to the Medicaid law in each of their states.

First Lab Whistleblower

Those readers of THE DARK REPORT with long memories will recall the whistleblower lawsuit filed by C. Jack Dowden against **National Health Laboratories, Inc.**, (NHL) back in 1990. After two years of investigation by the federal government, a settlement was announced at the end of 1992.

National Health pled guilty to two charges of submitting false claims to government health insurance programs. It paid a $1 million fine and its CEO, Robert E. Draper, was sentenced to jail time and a $500,000 fine. NHL also agreed to refund $111 million to Medicaid, Medicare and the Civilian Health and Medical Program.

That whistleblower lawsuit was the start of almost a full decade of enforcement actions against the laboratory testing industry. Officials at the **Department of Justice** (DOJ) dubbed their ongoing effort with the name "Operation Labscam." They eventually harvested about $1 billion in fines and amounts paid back to Medicare and other federal health programs.

In hindsight, it can be recognized that the Dowden whistleblower case against NHL marked a change in how federal healthcare officials viewed certain common lab industry sales practices. This included the unbundling of test panels when billing government and private payers. "Inducing physicians to order medically-unnecessary laboratory tests" became a target for federal enforcement.

The NHL whistleblower case demonstrates why one whistleblower lawsuit can radically alter how federal or state health program officials interpret laws and regulate a widely-accepted laboratory industry practice. The following example had a similar effect in changing the compliance activities of all clinical laboratories across the United States.

This notable laboratory whistleblower lawsuit involved **SmithKline Beecham Clinical Laboratories, Inc.** (SBCL). Filed in 1993 by Robert Merena, an employee in SBCL's billing department, the case was settled in 1998. SBCL agreed to pay $325 million to resolve the case. Merena spent another three years in acrimonious litigation with the Department of Justice (DOJ) before he received a relator's award of $26 million.

As they worked to settle this lawsuit, federal healthcare regulators decided to enact a requirement that every laboratory that was licensed as a Medicare or Medicaid provider would need to institute a compliance program. That requirement was a first for the lab test industry.

Lab Compliance Programs

Since that time, laboratories have devoted considerable time and resources to stay in compliance with this requirement. The need for every laboratory to maintain a conforming laboratory compliance program also created a new legal exposure for laboratory administrators, pathologists, and managers. These lab leaders can be personally liable whenever government health program investigators determine that they did not maintain an internal laboratory compliance program that met the standards defined by law.

As demonstrated by the examples provided in this intelligence briefing, laboratory whistleblower lawsuits can bring a definite change in how federal or state healthcare regulators enforce existing statutes. C. Jack Dowden's whistleblower lawsuit against NHL started what evolved into the DOJ's Operation Labscam to stop the practice of "lab test unbundling" and "inducing doctors to order medically-unnecessary tests."

Rob Merena's whistleblower lawsuit against SBCL led directly to new federal regulations requiring every laboratory serving the Medicare and Medicaid program to institute a formal laboratory compliance program.

Changes In California

Now we are watching the Hunter Lab/Riedel whistleblower lawsuit initially brought against seven laboratory companies in California change how the state's Medi-Cal officials enforce long-standing laws on "comparable pricing" when billing the Medi-Cal program. Is it possible that some of the other six states where similar whistleblower lawsuits are believed to be active could lead to a similar change in enforcement of their respective state laws on "comparable pricing" in cases of deeply-discounted lab test prices given to favored lab customers—but not to the Medicaid program?

At the same time, are there other lawsuits out there—whistleblowers, class actions, and the like—with the potential to trigger a substantial change in the operational and/or sales and marketing practices of clinical laboratories? In the example of the class action lawsuit that pits the Teamsters and the UFCW against Quest Diagnostics and Nichols Institute Diagnostics, the plaintiffs are potentially raising interesting legal issues associated with the manufacture, regulatory compliance, clinical performance, and marketing

Teamsters, UCFW Sue NID, Quest In Racketeering Case

Two unions file federal lawsuit and accuse nation's largest lab firm of violating RICO Laws

CEO SUMMARY: For the second time in recent years, Quest Diagnostics Incorporated and Nichols Institute Diagnostics (NID) face a lawsuit alleging problems with a number of diagnostic test kits that were manufactured and sold by NID going back to 2000. The plaintiffs are two unions—the Teamsters and the the United Food and Commercial Workers Union—who have filed a class action lawsuit alleging that the defendants violated the federal RICO act, among other claims. The lab firms deny the claims.

WHEN IT COMES TO FEDERAL RACKETEERING LAWSUITS, many people think back to the days when it was the mob and sometimes mob-influenced labor unions that were accused of violating the federal Racketeer Influenced and Corrupt Organizations Act, known as the RICO statute.

However, here's a odd twist on that theme. Two unions are accusing **Quest Diagnostics Incorporated** and **Nichols Institute Diagnostics** (NID, a wholly-owned subsidiary of Quest Diagnostics that was shut down in 2005) of market behavior that, among other causes of action alleged in the lawsuit, violates the Federal RICO law.

Moved To Dismiss Case

The RICO cause of action is one of 10 causes of action that is included in the amended complaint, which was refiled on August 8, 2010. The lawsuit was originally filed on April 15, 2010, in federal court for the Eastern District of New York. The defendants have moved to dismiss the case and Quest has denied the allegations at issue in the suit. *(See sidebar on page 9.)*

The plaintiffs are a pair of health funds for the two unions. One is the **International Brotherhood of Teamsters Local 456 Health and Welfare Trust Fund**. The other is **UFCW Local 1776 and Participating Employers Health and Welfare Fund**. The two plaintiffs are suing on their own behalf and on behalf of a class of persons described in the lawsuit.

What will be of interest to pathologists, laboratory administrators, and executives at *in vitro* diagnostics (IVD) companies are the plaintiffs' claims in this lawsuit. These claims center around the alleged non-performance of certain diagnostic test kits sold by NID for a period of time "between May 1, 2000 through the present," as described in the lawsuit.

Many clinical laboratories in the United States and other countries purchased and used diagnostic test kits sold by NID during the time referenced by plaintiffs in their lawsuit. Similarly, during these same years, a number of IVD companies competed intensely with Nichols Institute Diagnostics as it marketed its analyzer and its menu of test kits. It is likely that some IVD competitors to

NID are familiar with the allegations the plaintiffs are making in their lawsuit against Quest Diagnostics and NID.

These are among the reasons why both clinical laboratory professionals and IVD executives will want to understand the legal claims put forth by the Teamsters and the UFCW, on behalf of their health funds and the entire class they want to represent.

The simplest way to present these allegations is to quote directly from the plaintiffs' amended lawsuit. The following comes from page 2 of the amended complaint *(filed August 8, 2010)*:

NATURE OF CASE

6. This class action is brought on behalf of all entities in the United States and its territories, who, for purposes other than resale, purchased, reimbursed and/or paid for Intact PTH Kits, Bio-Intact PTH Kits, 25 OH-D Kits, ACTH Kits, and DHEA-S Kits (hereinafter, the "defective Nichols Kits") during the period between May 1, 2000 through the present.

7. Between May 1, 2000 and April 30, 2006 many of Defendants' Kits produced results that were materially inaccurate and unreliable, and thus medically unnecessary. Inaccurate results from Defendants' Kits led to overtreatment and unnecessary surgeries, which, in addition to the defective Kits themselves, were paid for in part or in full by Plaintiffs and Plaintiff Class members.

8. During much of that time, Defendants misled physicians, laboratories, and the medical community at large, by promoting the accuracy and reliability of their Kits, while failing to disclose defects of which they were aware.

9. Throughout, and possibly beyond, these six years of fraud, until federal regulators, the scientific community and the public caught up with Defendants' misconduct, consumers and third-party payers had paid for thousands of inaccurate tests and subsequent overtreatments and unnecessary surgeries for thousands of critically ill patients, costing hundreds of millions of dollars.

10. Consequently, Plaintiffs and all Plaintiff Class members seek damages as a result of their purchase of the aforementioned Kits.

Quest Diagnostics acknowledged the filing of this lawsuit. In each of its quarterly financial reports since the third quarter 2010, it has disclosed this class action lawsuit and wrote that:

In April 2010, a putative class action was filed against the Company and NID in the U.S. District Court for the Eastern District of New York on behalf of entities that allegedly purchased or paid for certain of NID's test kits. The complaint alleges that certain of NID's test kits were defective and that defendants, among other things, violated RICO and state consumer protection laws. The complaint alleges an unspecified amount of damages.

No other public statement issued by Quest Diagnostics about this class action lawsuit was located. In the past, however, Quest has strenuously denied the substance of these allegations, including that NID's test kits were defective or that patients suffered harm of any kind.

➤Class Action Lawsuit

This class action lawsuit filed by the Teamsters and UFCW is the second legal action that has named Quest Diagnostics and Nichols Institute Diagnostics as defendants and alleged that certain test kits made and sold by NID were "defective" during a period of time starting around 2000 and lasting through 2006.

Plaintiffs in the earlier legal case were *qui tam* relator Thomas Cantor and the Department of Justice (DOJ), which joined Cantor's suit after it was originally filed in federal court in 2004. This was the case that was resolved with a settlement that was announced on April 15, 2009.

For Quest and Nichols Institute Diagnostics, Class Action Lawsuit Is an Example of Déjà Vu

DÉJÀ VU IS PROBABLY A GOOD DESCRIPTION of the reaction that executives from the nation's largest laboratory testing company had last year when they learned that chapters of two national labor unions had filed a class action suit naming Quest Diagnostics Incorporated and Nichols Institute Diagnostics (NID) as defendants.

That's because the date of this newest court filing was April 15, 2010, exactly one year to the day that Quest Diagnostics and NID had announced a settlement with the United States Department of Justice (DOJ) and whistleblower Thomas Cantor. That settlement was to resolve allegations involving certain diagnostic test kits made and sold by NID for a period lasting between 2000 and 2006.

Now, on the one-year anniversary of a settlement with the DOJ and federal health programs that totaled more than $300 million, executives at Quest Diagnostics found themselves facing a second legal action that alleged similar claims as had whistleblower Thomas Cantor in his *qui tam* lawsuit.

Global Settlement

As part of the global settlement with the Department of Justice, Quest Diagnostics and NID paid a total of $302 million to resolve all the allegations. Of this total, $40 million was a criminal fine paid by Nichols Institute Diagnostics as part of its guilty plea. The DOJ press release described it as a "felony misbranding charge in violation of the Food, Drug and Cosmetic Act relating to NID's Nichols Advantage Chemiluminescence Intact Parathyroid Hormone Immunoassay, a test that was used by laboratories throughout the country to measure parathyroid hormone (PTH) levels in patients."

In describing the civil settlement, the DOJ wrote that "Quest and NID will pay the United States $262 million plus interest to resolve False Claims Act allegations relating to the Advantage Intact PTH assay and four other assays manufactured by NID that allegedly provided inaccurate and unreliable results."

Quest Diagnostics admitted no wrongdoing and denied the DOJ's allegations in settling the civil action. In its April 15, 2009, press release about this settlement, Quest Diagnostics wrote that "While the company disagrees with and does not admit to the government's civil allegations, it agreed to the settlement to put the matter behind it." In that same press release, Michael E. Prevoznik, Senior Vice President and General Counsel of Quest Diagnostics, was quoted as saying "Quest Diagnostics conducts its business with the highest standards of quality and integrity, and we regard NID's failure to meet our standards as unacceptable."

Quest also emphasized that it, as distinct from its defunct subsidiary NID, was never charged with any crime, nor did Quest plead guilty to any crime. Although, in its civil action, the DOJ alleged that Quest through NID distributed defective test kits, Quest denied the tests were defective. And Quest has denied that any patients were harmed by NID's tests, noting that the DOJ did not ultimately make such a finding.

So, it is ironic that exactly one year after this settlement involving government health programs, plaintiffs representing private health insurance plans have filed a class action lawsuit to pursue similar allegations. As in the Cantor/DOJ case, these plaintiffs claim they paid for diagnostic test kits that were defective.

In page three of their class action lawsuit, attorneys for the plaintiffs claim that "Throughout, and possibly beyond, these six years of fraud, ...consumers and third-party payers had paid for thousands of inaccurate tests and subsequent overtreatments and unnecessary surgeries for thousands of critically ill patients, costing hundreds of millions of dollars."

That allegation sets a strong battle line between the plaintiffs and the defendants in this case. This could be a high-stakes legal case. That's because the defendants paid a total of $262 million to settle the allegations in the civil *qui tam* case initiated by Thomas Cantor in 2005. Maybe the lawyers for the Teamsters and UFCW, as plaintiffs, are hoping for their own déjà vu in terms of an eventual settlement.

Now, for the second time in as many years, attorneys for Quest Diagnostics and Nichols Institute Diagnostics must square off against plaintiffs alleging torts associated with the diagnostic kits manufactured and sold by NID. In this class action lawsuit, there are several distinctive features that bear watching by laboratory professionals, IVD executives, and health insurance managers.

Lawsuit Has Differences

For one, the causes of action in this class action are fundamentally different than the causes of action that made up the majority of the *qui tam* lawsuits filed over the past two decades that were unsealed and made public. These lawsuits commonly involved allegations that a laboratory had inappropriately billed and submitted claims to federal health programs, including Medicare, Medicaid, and CHAMPUS (now called TRICARE).

Typically, it would be argued that the claims in question were violations of federal statutes for false claims and anti-kickback activity. There was no allegation that care provided a patient, for example, was negatively affected because a laboratory had offered inducements to a physician client in exchange for that physician's Medicare patient referrals.

Cantor's *Qui Tam* Lawsuit

That was not the case in the *qui tam* lawsuit filed by Thomas Cantor. This lawsuit alleged that certain diagnostic kits manufactured and sold by the NID during a specified number of years produced inaccurate results. The alleged failure of the diagnostic test kit to produce a test result that was consistent with its label as specified by the Food, Drug and Cosmetic Act was one basis for plaintiffs to define each resulting claim for service as a false claim.

Cantor's whistleblower lawsuit further alleged that, when physicians relied on these inaccurate results, some patients may have received unnecessary care. That allegation is also contained in the class action lawsuit filed by the Teamsters and the UFCW.

In the past two decades, THE DARK REPORT is unaware of any major class action law suit that was: 1) based on some type of failure of, say, an FDA-cleared diagnostic test kit or a laboratory-developed test (LDT); and, alleged that the inaccurate lab test results produced when these tests were performed could have caused patients to be misdiagnosed, get care that was unnecessary, or even to get care that possibly proved lifechanging to the patient.

Thus, the class action suit filed by the Teamsters and the UFCW, which alleges that these types of consequences resulted as providers used the diagnostic test kits in question, has the potential to be a landmark legal case, if the plaintiffs can get past the defendants' pending motion to dismiss.

In the *qui tam* lawsuit filed by Thomas Cantor, it was alleged that certain diagnostic kits manufactured and sold by the plaintiffs during a specified number of years produced inaccurate results.

For the lab industry, both the *qui tam* lawsuit filed by Thomas Cantor and the current class action lawsuit filed by the Teamsters and the UFCW appear to have interesting and relevant legal issues for manufacturers of diagnostic test kits and for laboratories that purchase and use those kits. Also, because such kits must perform equivalent to FDA-approved assays, this may be another legal issue.

Moreover, should this class action lawsuit actually make it to trial, it would be quite a courtroom drama to watch as lawyers representing the Teamsters union scrap with the tough battery of attorneys that look out for Quest Diagnostics' corporate interests. TDR

Crossing State Lines With Digital Pathology

Pathologists in Washington provide hospital in rural Alaska with full range of AP services

CEO SUMMARY: It is predicted that use of digital pathology will create new care models in the profession of anatomic pathology. An early example of this trend can be found in Bellingham, Washington. Here, the 10 pathologists of Northwest Pathology are using a digital pathology system to provide frozen section and surgical pathology services to a rural hospital located more than 600 miles away in Alaska. This arrangement gets high marks from the hospital, as well as its physicians and patients.

IT'S A BRAVE NEW WORLD IN PATHOLOGY when pathologists working in Washington can remotely provide the full range of surgical pathology services to a rural hospital in Alaska. Credit digital pathology as the technology which makes this long-distance arrangement successful.

For more than two years, **Northwest Pathology** in Bellingham, Washington, has been the pathology service provider to rural **Ketchikan General Hospital** in Ketchikan, Alaska. The use of digital pathology to support this unusual clinical relationship has been given wide coverage in local and national news outlets.

Pathologists in Washington are using a sophisticated digital pathology system to remotely provide a full range of surgical pathology services to Ketchikan General. Both parties to the arrangement say it has been successful at making clinical care available to patients in this rural area.

But there is more to this story than the simple use of digital pathology to provide surgical pathology services across state lines. The 10 pathologists at Northwest Pathology have a sophisticated business understanding of the market. They are willing to pioneer the use of digital pathology to support an innovative strategy to position the group for long term success in the competitive marketplace.

Last May, at the *Executive War College on Laboratory and Pathology Management*, Berle Stratton, M.D., FCAP, a cytopathologist with Northwest Pathology, laid out the group's strategy and details about using digital pathology to provide pathology services across state lines.

Discussions for One Year

"In recent years, our group has provided onsite coverage at 49-bed **Ketchikan General Hospital**," he said. "Once or twice each month we would send a pathologist there. Pathologists in our group would take turns rotating up to Ketchikan.

"Typically, the pathologist's trip to Ketchikan would consume two days that week," explained Stratton. "Although Northwest Pathology was eager and capably provided on-site service, there were challenges to supporting this relationship—both in the travel to and from Ketchikan, as

well as the need for the Bellingham office to cover the work of the pathologist who was out of the office. Additionally, Ketchikan General Hospital was paying the travel expenses."

To address these challenges, Stratton said that his pathology group spent more than a year looking at different service models they could use to deliver top-flight anatomic pathology services to the hospital in Ketchikan.

Digital Pathology Solution

"Digital pathology quickly emerged as a promising solution," noted Stratton. "It was vigorously studied and debated within our pathology group. We quickly recognized that the test volumes from intraoperative consults originating from Ketchikan Hospital were not enough to fully support the economics of using digital pathology.

"On the other hand, our pathologists recognized how our group is positioned to serve many of the communities in Alaska and the Pacific Northwest by using digital scanning and digital pathology systems," he continued. "We had already eliminated lots of paper within our lab by our use of computers and our LIS (laboratory information system). So we felt we had the foundation of an information technology platform already in place. Thus, moving to digital pathology would simply be an extension of what we already do.

"We decided to take the plunge and lease a digital pathology system from **Aperio Technologies, Inc.**," stated Stratton. "Our monthly cost is in the range of $3,500 per month and the specimen volume generated from Ketchikan General Hospital does not fully cover this cost."

However, this forward-looking pathology group was willing to make the investment to provide a higher level of service to this rural hospital while managing physician time more effectively. "Northwest Pathology views its contract with Ketchikan General Hospital as strategically important," noted Stratton. "We are also considered other business relationships that could leverage our abilities with digital pathology and could allow us to serve new clients in communities.

"For our group, being able to offer telepathology is an important marketing tool to have in our quiver," he explained. "Although Northwest Pathology already served the Ketchikan community, we now provide a value-added service of telepathology 40 hours per week. To further enhance our service to a valued client, we are willing to fund something that will not pay for itself. We view it as the cost of doing business.

"But there is more to this analysis than simply cost-versus-revenue," commented Stratton. "Telepathology gives us a way to approach a potential new client that is a critical access hospital or a smaller client that is not a critical access hospital.

"The geographical location of these potential hospital clients could be anywhere," observed Stratton. "They could be in Alaska, in Nebraska, or in Maine. It doesn't matter. In this way, digital pathology positions us with an effective service edge—both now and for the future."

The working relationship between Ketchikan and Bellingham is straightforward. It shows how digital pathology is already contributing to new business models in anatomic pathology that can benefit community hospital-based pathology groups.

Frozen Sections or Cytology

"At its own expense, Northwest Pathology installed an Aperio scanner at the hospital in Ketchikan," observed Stratton. "For intraoperative frozen sections or cytology preparations, a histotechnologist uses this scanner to make whole slide digital images.

"Next, the technologist uses a secure Internet connection to make the images available to the pathologists at Northwest Pathology, in Bellingham, which is 600 miles to the south of Ketchikan, in Washington State," he noted. "This gives our pathologists immediate access to the images. They can convey a timely and accu-

Digital Pathology Helps Pathology Group Improve Clinical Services Across State Lines

DIGITAL PATHOLOGY WAS AN EFFECTIVE WAY to improve service with its rural hospital client in Alaska, even if, in the short term, the economics don't fully balance out for the pathologists at Northwest Pathology, located in Bellingham, Washington.

"From the start, we recognized that reimbursement from the small number of frozen sections generated by a 49-bed rural hospital in Alaska would not fully cover the monthly cost of leasing a digital scanner for that site," observed Berle Stratton, M.D., a cytopathologist with Northwest Pathology. "But we view this initiative as part of our strategic relationship with the hospital. This is where our quality stewardship comes into play.

"As a pathology group, we believe it is important to improve quality and service in a way that distinguishes our laboratory," he said. "Another consideration was to raise our value to this community and improve the value we deliver to that hospital on a daily basis.

"For these reasons, this system promotes our strategic and quality interests even if the finances don't quite pencil out on the intraoperative consultations that we do," he observed. "If you compare only the revenue we get for intraoperative consults versus the cost of doing telepathology, we don't recover the cost for that clinical service. But that is only part of the total relationship our pathology group has with the hospital."

Stratton pointed out that the intraoperative consults (frozen sections) are the service anchor which supports the entire relationship Northwest Pathology maintains with the hospital. "For our client, Ketchikan General Hospital, intraoperative consults enabled by digital pathology is a value-added service that helps the hospital build patient volume and generate revenue. For us, our level and character of service distinguishes Northwest Pathology as a valued partner to critical access hospitals and other smaller enterprises.

"We continue to go to Ketchikan once a month to be a part of the medical staff meetings, for inspections, and to foster our relationship with the administration, the medical staff and the lab personnel," noted Stratton. "However, before implementing digital pathology to support intraoperative consults, we often needed to go a second time in a month. Thus, use of digital pathology has eliminated those second trips. That is a direct economic benefit for the hospital, which pays for this travel, and our group, which must cover for the pathologist who is out of our office during the two days of travel."

rate diagnosis to the surgeon at the remote hospital.

"The strategic aspects of this operation are important to us because we do all of the anatomic pathology for Ketchikan General Hospital," Stratton explained. "The number of intraoperative consults from Ketchikan General has approximately doubled in the year since we introduced the digital pathology-based service.

"This shows how the hospital has the opportunity to retain or enhance those procedures for the physicians involved and the administration at the hospital," he said. "If we didn't provide this service, those surgical patients may have been sent to another facility. That's a huge benefit for that hospital.

"It's also value-added in the community," continued Stratton. "Patients who might have needed to travel for certain medical procedures can now stay in Ketchikan and be close to home and family. Telepathology represents an incremental improvement to quality and patient satisfaction. It's one way our pathology group supports patient-centered care.

"Now, even though our consultation volume has doubled, these are small numbers for frozen sections and cytology," Stratton continued. "But for the hospital,

small numbers of additional surgeries and a small number of more complex surgeries can be significant because Ketchikan General is a critical access hospital.

"Critical access hospitals are reimbursed on a cost basis, and rates for these hospitals are higher than the DRG (diagnosis-related group) rates that most hospitals receive," explained Stratton. "Therefore, retaining or enhancing those surgeries is significant for Ketchikan General.

Low Volume, High Quality

"As mentioned, the volume is not great," he said. "But we offer fast turnaround time because the scanning and transmission of the digital images adds only five or six minutes to the time it would take to view those images locally.

"Physicians at the hospital are most supportive of the digital pathology arrangement," he said. "For one thing, it increases the number of hours per week available for them to schedule procedures with anticipated intraoperative consultation. It also allows pathologist intervention for procedures when the need for intraoperative consultation had not been anticipated. This is patient-centered medicine, and it also boosts their productivity.

"Several marketing aspects of this digital pathology arrangement are significant for us," commented Stratton. "One, the hospital is pleased that we have installed this equipment in their hospital. Two, the hospital and medical staff are happy as they retain patients who remain in the community for their care.

"Three, the patients are pleased with it as well," he said. "They recognize that it enables them to get treatment in their own local hospital and avoid lengthy travel to another hospital in a bigger community."

It didn't take long for the word about the digital pathology arrangement to make news headlines. "As soon as we implemented this system in Ketchikan, there were newspaper articles published throughout Southeast Alaska," recalled Stratton. "The work that we do for the Ketchikan General Hospital created a lot of buzz for Ketchikan and it created quite a bit of coverage about how an urban pathology group could work with rural hospitals in southeast Alaska to enhance patient care.

"Without having us to do this work, the hospital could lose those patients to another facility in another town in Alaska or to another facility in Washington State." he added. "That's significant for them.

"Because each of us traveled to Ketchikan regularly, we are all licensed to practice in Alaska, as required by the state, to remotely interpret specimens originating from Alaskan patients," he noted. "We are also fully credentialed and privileged to practice at Ketchikan General, as required by the hospital medical staff bylaws. It is important to note that licensure requirements for remote pathology interpretation vary by state.

"Although quality of care is paramount to us, our decision to engage digital pathology to support this client relationship was also justified on strategic and customer-service grounds," Stratton commented. "First, we enhance service to a valued client in an important rural community. Second, we have a strong footprint in Southeast Alaska. Further, by working this way, we can support the strategic interests of the hospital. In summary, telepathology represents an incremental improvement in our stewardship and service rendered to Ketchikan and Southeast Alaska."

First-Mover Advantage

Other community hospital-based pathology groups should study the successful use of digital pathology by Northwest Pathology. First-mover and early-adopter pathologists will likely gain competitive advantage when they deploy digital pathology in intelligent ways, such as Northwest Pathology has done to support Ketchikan General Hospital. TDR

Contact L. Berle Stratton, M.D., at 360-734-2800 or berle.stratton@northwestpathology.com.

Lab Briefs

DMETRIX PREPARES TO INTRODUCE CHEAPER PATHOLOGY SCANNER

PATHOLOGISTS MAY SOON BE ABLE TO PURCHASE a smaller and less expensive digital scanning system that fits on a microscope. **DMetrix, Inc.**, of Tucson, Arizona, is working to downsize its flagship digital pathology imaging system.

Pixuan "Joe" Zhou, Ph.D, is President of DMetrix. He recently told a reporter for the *Arizona Daily Star* that the company's strategy is to downsize its imaging system. The goal is to develop a scanning platform, or stage, that fits on the standard microscope. This scanning platform would interface to DMetrix's digital imaging software and will be priced at just a third of the $250,000 cost of the DMetrix DX-40, which he says is the fastest digital pathology scanning system in the marketplace today.

The technology used by DMetrix was developed by scientists at the **University of Arizona**. The team included Michael Descour, Ph.D., Professor of Optics Sciences, and Ronald Weinstein, M.D., Professor of Pathology and a founding director of the Arizona Telemedicine Program.

BIO-REFERENCE LABS ROLLING OUT NEW DESIGN FOR COLLECTION CENTERS

ALL 87 PATIENT SERVICE CENTERS (PSC) operated by **Bio-Reference Laboratories, Inc.** (BRLI), are slated to be upgraded to a new, patient-friendly design. The project will require $1 million and take five years.

Key elements of the new design include leather furniture in the reception areas, flat screen televisions, designated play areas for children, and softer lighting. There will also be a genetics consultation room at each PSC.

The genetics consultation room will be equipped with Skype, which allows video and voice calls over the Internet. This capability will permit BRLI's patients to consult with genetics consultants. BRLI has a fast-growing business in genetic testing.

BRLI's strategy to upgrade its patient service centers is notable for several reasons. First, it shows how one lab can raise the competitive bar. If BRLI improves the patient experience at its PSCs, it can enjoy greater loyalty from its patients and referring physicians.

Second, the investment of more than $1 million to upgrade all its PSCs demonstrates BRLI's willingness to maintain its public face. Just as a hotel needs to refresh its guest rooms and public areas every few years, so also do clinical laboratories need to refresh the facilities visited regularly by patients.

Third, the addition of a genetics consultation room in every BRLI patient service center is a noteworthy marker for the take-up of genetic testing by physicians and patients. BRLI wants to hold its first-mover advantage in the market by improving patient access to its genetic counselors, as well as to the pathologists and geneticists who perform these tests.

US CLINICAL LABS ACQUIRES VLS

US CLINICAL LABORATORIES OF HOUSTON, TEXAS, announced its acquisition of **Vidalia Lab Services** (VLS) of Vidalia, Georgia, a company that serves nursing homes and skilled nursing facilities (SNF).

Rod Proto, CEO of US Clinical Labs (USCL), noted that VLS provides lab testing services to 45 counties in Southern Georgia. US Clinical Laboratories has been in business for one year. The laboratory testing company operates four lab testing facilities. It has 12 patient service centers that are located in two states. TDR

Michigan's JVHL Partners With AMA to Use LOINC

➤Covisint, AMA offering LOINC-based system that helps JVHL member labs connect to physicians

➤➤CEO SUMMARY: Office-based physicians in Michigan can use a program offered by the American Medical Association (AMA) to get assistance in adapting their electronic medical record (EMR) systems to utilize LOINC for lab test ordering and lab test results reporting. This service is offered by Amagine, Inc., which is a partnership between AMA and Covisint, a division of Compuware. Joint Venture Hospital Laboratories (JVHL), with its 130 hospital lab members, is collaborating with Amagine and Covisint.

IN MICHIGAN, A STATEWIDE PROJECT is about to launch that will use **Amagine, Inc.**, a new portal service, to give 22,000 physicians in the Wolverine State an improved ability to use LOINC to handle laboratory test data. This portal enables the use of LOINC when the participating physician places laboratory test orders and receives back the lab test data.

Among other benefits, this standardization can help local clinical laboratories and pathology groups maintain and improve their access to office-based physicians in their communities. As well, this project is another step forward on the road to creating an information technology (IT) platform that automatically standardizes lab orders and results for physicians, payers, and health information exchanges (HIE).

Hospital laboratories are playing a key role in this project via an information technology relationship between **Joint Venture Hospital Laboratories** (JVHL) and **Covisint**, a business unit of publicly-traded **Compuware**. The new LOINC tool will be part of a package offered to physicians by Amagine, which itself is a collaboration involving the **American Medical Association** (AMA) and Covisint. Sponsoring the introduction of Amagine in Michigan is the **Michigan State Medical Society**.

All the collaborators involved in this project recognize how the expanded use of LOINC—Logical Observation Identifier Names and Codes—by office-based physicians can contribute to better integration of healthcare services. LOINC is a database that provides universal identifiers for lab test results and other associated data. LOINC is managed by the **Regenstrief Institute**, a nonprofit medical research organization at **Indiana University** in Bloomington, Indiana.

➤Benefits From Use Of LOINC

"Amagine and Covisint have a LOINC solution that can directly benefit local clinical labs and pathology groups," said Jeff Beamsley, who is Director, Partner Programs, at Covisint. "We are building a computerized physician order entry (CPOE) tool that orders in LOINC and can translate the local lab's native nomenclature. In this way, labs can keep their local language while conversing in LOINC with their client physician's CPOE tool.

Michigan Hospital Labs Use Unique Test Codes That JVHL Then Translates By Using LOINC

YEARS AGO, LOINC CAPABILITY was established by Joint Venture Hospital Laboratories (JVHL). The regional laboratory network, which serves 130 hospital laboratories in Michigan, uses LOINC to provide a single-source report of laboratory test results data to managed care plans in the state, among other uses.

"We work with our hospital labs' internal test identification systems because many hospitals don't yet have LOINC coding systems up and running," said JVHL Executive Director Jack Shaw.

"We already have an internal algorithm to crosswalk those various internal codes to the appropriate LOINC code for the test results that we collect for payers and physician groups' care management programs," Shaw added. "It is the easiest way for us to provide standardized test nomenclature and standardized reference ranges when managing lab test data coming from our 130 hospital labs.

"JVHL's experience in creating LOINC translation made us a very good partner to Covisint as they move forward with the American Medical Association (AMA) to help physicians in Michigan and elsewhere use LOINC coding in their Amagine program," Shaw said.

"LOINC allows regional and national health plans to merge all their lab test data from across the country and use that data for quality improvement, for disease management, and for physician-incentive programs," Shaw explained. "In Michigan, we see additional value as Covisint helps convert Michigan physicians to LOINC. Wider adoption of LOINC helps the health plans in Michigan and it benefits JVHL as well.

"JVHL's contracts with health plans have parameters defining how quickly we are to submit lab test data to them," observed Shaw.

"These payers want the lab test results reported to them quickly for purposes of disease management, pay for performance, and quality improvement," he said.

"As more physicians become 'LOINC capable,' this will help JVHL deliver accurate data more quickly, and so it will absolutely assist us," Shaw concluded.

"JVHL is a natural collaborator in this project because it already has the LOINC translation tables in place," he went on. "JVHL actively and regularly uses LOINC with its 130 hospital laboratory members."

By using LOINC for standardization of lab test orders and lab test results, Covisint and JVHL will allow a seamless exchange of lab data. In turn, this will help physicians meet the federal government's meaningful use (MU) criteria. LOINC also gives the hospitals and participating physicians lab test data in a standardized electronic format that they can use in important ways.

For example, this standardized lab test data can be used to satisfy quality reporting mandates or help the provider qualify for performance incentives. LOINC-standardized lab test data makes it easier for providers to accommodate the shift to accountable care organizations (ACO), medical homes, and other collaborative care approaches.

LOINC offers a number of significant advantages for labs and for all providers. "The lack of standardization in the nomenclature and reference ranges for the same laboratory test is a major challenge," stated Beamsley.

"Individual laboratories internally use different test codes and varying normal ranges for the same assay," he noted. "This challenges care management systems that want a full and accurate picture of an individual's care in the community.

"Similarly, take the example of a study to determine community-wide performance in managing a chronic disease—such as hypertension or diabetes—and compare that with how other communities in the country are managing the same disease," continued Beamsley. "There is a need for an apples-to-apples comparison of the lab test data produced in these different communities.

Benefits From Use Of LOINC

"LOINC adds precision to these activities," he added. "Lab test data in the LOINC format helps physicians and researchers understand the test results produced from different labs.

"The need for standardization in the naming of the laboratory tests and their reference ranges is becoming more of a priority as the integration of clinical care moves forward," stated Beamsley. "Increasingly, we will want to know how one downtown Detroit clinic is doing in managing its population of patients with diabetes versus the national average."

Jack Shaw, Executive Director at JVHL, recognizes the need for local laboratories to better utilize LOINC. "Historically, hospital labs have developed their own unique in-house codes," he said. "This has restricted the utility of laboratory data outside each individual hospital's environment.

"We expect this new IT initiative will help change that," noted Shaw. "Utilizing LOINC as the universal lab test identifier will put Michigan ahead of other states because so few physicians and labs currently use LOINC routinely."

JVHL is distinctive because it is one of the first multi-laboratory organizations in the nation to provide LOINC to the 130-member hospital labs in its consortium. "JVHL is an interesting model that allows a consortium of local and regional labs that appear to payers as one big lab," Beamsley explained.

"As a result they compete very effectively against the national labs," he said. "One reason they compete so well is they provide a pathway to LOINC."

The first step in this project uses LOINC in lab ordering and resulting through the Amagine portal. Future enhancements could include a LOINC translation service for all EMRs, a step that could improve the ability of local labs to compete with national labs.

"Right now, EMRs are struggling to achieve effective point-to-point integration with medical laboratories," explained Beamsley. "It requires significant time and expense for a laboratory to connect to a physician's EMR.

"**Laboratory Corporation of America** and **Quest Diagnostics Incorporated** have an advantage over local labs when it comes to EMR integration," he said. "That's because many EMR vendors have already programmed the test compendiums of the national labs into their EMR products.

"By contrast, local laboratories that want to have their unique compendium of lab test codes loaded into the physician's EMR and have that EMR tie into their LIS must typically pay between $2,000 to $20,000 per physician office for projects that may take six months to complete," he said. "This time and expense adds up quickly for the local laboratory which must integrate with the EMRs for each of its office-based physician clients.

LOINC Codes

"We know that, when the physician's EMR is able to use a standard set of LOINC codes that are either: 1) accepted directly by the labs; or, 2) there is some translation layer available that's external, then both labs and physicians can more quickly achieve a workable interface between the lab's LIS and the physician's EMR," stated Beamsley. "It also greatly reduces the time and expense typically required to achieve that function." TDR

Contact Jack Shaw at 313-271-3692 or jshaw@jvhl.org; Jeff Beamsley at 313-227-6221 or jeff.beamsley@covisint.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Two laboratory companies based in Spokane, Washington, were recently recognized in a list of Washington State's "100 Best Companies to Work For" in 2011. One was **Incyte Pathology, Inc.**, an anatomic pathology group. The other was P**athology Associates Medical Laboratories** (PAML). The list was compiled by *Seattle Business* magazine. Over 300 companies were involved in the selection process, which took five months to complete.

YALE STUDY SAYS BREAST CANCER ER TESTS MISCLASSIFY PATIENTS

Estrogen Receptor (ER) testing for breast cancer patients was the subject of a study by researchers at the **Yale Cancer Center**. They determined that between 10% and 20% of breast cancers classified as ER negative by conventional test methods are actually positive. These findings were published in the June 28 issue of the *Journal of Clinical Oncology*. The study team was led by David Rimm, M.D., Professor of Pathology at **Yale School of Medicine**. His team is working to develop a new method for standardizing ER measurement. They are developing a "novel method to detect the estrogen receptor that uses fluorescent detection in conjunction with a series of standard controls." Their work indicates that this method is more sensitive and reproducible.

PHYSICIAN MARK-UP OF LAB TESTS IS GLOBAL ISSUE

Physician mark-up of laboratory tests performed by an outside medical laboratory is not unique to the United States. The same practice exists in Bangladesh, where it is called the "commission trade." Pathologists in that country are speaking out against the practice and calling for both "unified fees" for pathologists and quality ratings for diagnostics centers. As reported by *bdnews23.com*, a news outlet in Bangladesh, these issues were discussed at the **Bangladesh Society of Pathologists'** (BSP) 29th national convention. Pathologist Professor M.D. Shamiul Islam Sadi, General Secretary of the BSP, said "It's unethical to prescribe medical tests in exchange of commission from the diagnostic center." Sadi also bemoaned the lack of a national accreditation or licensing program in Bangladesh, noting that "As there is no accreditation and unified fee system, different diagnostic centers charge differently for same services."

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