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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

Pick Your Medicine: Personalized or Precision?

DURING THE PERSONALIZED MEDICINE WORLD CONFERENCE (PMWC) that took place in Silicon Valley last week, there was much excitement about the earliest clinical services that meet the definition of personalized medicine.

It won't surprise pathologists and lab administrators to learn that companion diagnostics is considered a frontline example of personalized medicine. Our Editor-In-Chief, Robert L. Michel, was at the PMWC. Upon his return to the office, he shared with me some fascinating insights about the presentations that took place at this annual conference, which attracted more than 900 participants. *(See pages 8-9 in this issue.)*

Of all the interesting points, the one that jumped out at me was Michel's report of one speaker's presentation, where he said that "personalized medicine" is a term that is becoming passé. It was this speaker's assertion that the term "precision medicine" is gaining favor because it is more descriptive of a clinical procedure that, by definition, is totally unique to the individual patient.

Curious about this, I decided to do what most of us now do when we want to learn more about a subject. I googled it. (Yes! "To google" is a verb and I am confident that you understood my reference.) After entering "precision medicine," Google returned 54.8 million results.

That caught me by surprise. These search results demonstrate the widening circle of health policy experts, physicians, and clinical leaders who use this term—precision medicine—along with personalized medicine. Upon reflection, this makes sense to me. Precision medicine connotes a sense of both increased accuracy and increased customization that directly benefits the individual patient.

Moreover, precision medicine is a descriptor that plays to the strengths of clinical laboratory testing and anatomic pathology. After all, one cornerstone of laboratory medicine is that every patient is unique and it is the pathologist, the Ph.D., and the laboratory scientist who interpret a patient's lab test results with the goal of guiding the referring physician to an accurate diagnosis.

The more I think about it, the more I prefer "precision medicine" over "personalized medicine." However, I will leave it to you to pick your medicine: personalized or precision. Regardless of your preference, the important point is that these terms describe a healthcare-wide transformation that will elevate the value that clinical laboratory testing provides to physicians and patients. TDR

Form 5010 Changeover Causing Payment Delays

Transition to new form began on January 1, 2012, most laboratories can expect to see revenue shortfall

CEO SUMMARY: Even after testing compliance with HIPAA Form 5010 for more than a year, one out of four payers is not ready to pay claims using this new form. Claims payment experts are telling clinical labs to expect some shortfall of revenue in coming weeks as payers struggle to program their systems to cleanly handle claims submitted on 5010 forms. Executives from XIFIN, Inc., and Gateway EDI, Inc., offer insights and recommendations as to how labs can deal with a less than ideal situation.

BECAUSE MANY PAYERS were not fully ready to implement HIPAA Form 5010—which became mandatory on January 1, 2012—approximately 9% TO 20% of laboratory test claims are going unpaid.

That's the estimate of claims payment experts who spoke during an audio conference on January 18 sponsored by THE DARK REPORT. If there is good news in these developments, it is that the larger proportion of claims filed with Form 5010 are being paid without a problem.

However, there is some bad news, because certain payers were not fully prepared for Form 5010 implementation on January 1. These experts predict that it is most likely that most clinical laboratories and pathology groups will experience a shortfall in revenue of some significance in the coming weeks.

"As an industry, we're probably at the most painful part of 5010, which is the transition," said Matt Warner, Associate Vice President of Operations at **XIFIN, Inc.,** a company in San Diego that assists labs and other providers in getting paid.

"But the bigger problem is that the burden of compliance is borne disproportionately by providers. Providers risk lost revenue due to timely filing limits if billing is not prompt and accurate.

"Payers have far fewer incentives to comply with the standards," explained Warner. "After all, if providers, including laboratories, are unable to resubmit claims within the required window of time, it means payers simply make fewer payouts."

Lâle White, Executive Chair and CEO of XIFIN, agreed. "The business impact for the 5010 production can be extraordi-

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

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narily significant for laboratories," she stated. "It could translate into lost revenue or late revenue, and increased costs.

"If needed, resubmission of claims could be delayed as labs research the issues behind rejections of the claims in question," continued White. "These glitches are inevitable, so the real issue is that every lab must be prepared to deal with them rapidly and promptly.

"Based on our experience with our laboratory clients, approximately 91% of claims volume is using 5010 forms" she noted. "By contrast, only 75% of the payers are in production and prepared to accept 5010 claims. Further, among our payers, 7% remain in the testing phase, 5% have completed testing and are about to go live, and 11% of payers are still not ready to do testing.

Some Payers Unprepared

"Generally, it is the smaller payers that are still not fully capable of accepting and processing 5010 claims, and their number is significant," added White. "Fortunately, this group of payers represents just a small portion of all claims being filed by providers.

"For this reason, we believe that the payers not ready for Form 5010 testing represent only 2% of claims," she said. "Payers now in the progress of 5010 testing represent about 6% of claims. About 1% of payers have completed testing but are not yet paying claims using Form 5010.

"In this healthcare-wide conversion, the obvious goal of every clinical lab and pathology group is to have no interruption in the revenue stream," explained White. "However, it is naïve to suggest that labs would not experience any interruption whatsoever.

"Remember, this is a significant transition," she continued. "The last transition in submission and remittance was seven years ago. That was when Form 4010 was introduced. To get through Form 5010 implementation, the billing departments of labs need to be on the alert to identify the different kinds of problems, then address them in the most effective and efficient manner."

Form 5010 Claims Unpaid

Unpaid claims are also being observed at **Gateway EDI**, a large claims payment clearinghouse in St. Louis, Missouri. "Of all the common problems experienced by labs, the biggest is unpaid claims," stated Jackie Griffin, Director of Client Services, Training and Project Implementation at Gateway EDI. "An estimated 20% of claims were going unpaid as of January 18—even though the volume of claims paid successfully has been rising since the January 1 effective date of 5010 implementation.

"Gateway began the transition to 5010 in November," she explained. "As of today (January 18), we have about 80% of our claim volume going out via 5010. We have migrated all Medicare contractors for Part A and B and most Blue Cross/Blue Shield plans. We also migrated the Medicaid programs that were ready and all large commercial payers.

"That 80% of our claim volume is going to large payers," Griffin noted. "That's about 1,100 of our 2,700 payers. The other 1,600 payers have been approved to use Form 5010 and Gateway EDI is in the process of scheduling production dates to get them switched over."

Form 5010 Claims Unpaid

Like the team at XIFIN, Gateway EDI recognizes that some payers have yet to bring up their systems to accommodate Form 5010 claim submissions. "A certain percentage of payers are still testing," she added. "We are waiting for approximately 70 more payers to make plans with us to begin accepting claims submitted on 5010 forms."

To stay ahead of these developments and protect cash flow, clinical labs and

pathology groups are advised to take three specific steps. "Step one is to be sure that you have the resources and expertise in-house to review payment files adequately," advised White. "The goal here is to have knowledgeable people in your billing department who can speedily and accurately recognize the issues that surface, then work effectively with the payers involved to address those problems.

"Step two is to have surveillance tools and processes in place to quickly identify issues," she continued. "Your lab's billing team should have a defined process that allows them to spot problems, then develop an action plan to address those specific issues with the individual payers.

"Step three involves the relationship your lab has with individual payers," she stated. "It is essential to have the proper contacts and influence within each payer so your billing team can quickly resolve issues and restore timely payments flowing back to your laboratory.

Inundated With Questions

White summarized the situation with an observation and a recommendation. "Unfortunately, many payers are inundated with questions," she said. "Their call centers are overburdened and their service teams are unable to answer calls.

"At the moment, the transition to Form 2010 is overwhelming payers with a flood of issues that surface as tens of thousands of providers submit claims," White explained. "Thus, the single most important thing labs can do is to carefully scrutinize all payments as they come in—and throughout the transition period—to make sure they are being paid accurately and appropriately within their contracted guidelines.

"Remember, this time period is not 'business as usual' for any payer," concluded White. "Therefore, the laboratory should be prepared to act promptly as it receives claims, identifies problems, and, prepares to resubmit claims. Prompt attention and action in this regard will help the lab avoid significant interruption in payment remittals by payers." TDR

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—By Joseph Burns

Biggest Payers Ready For Form 5010 Claims

MOST OF THE NATION'S largest payers have completed the transition to HIPAA Form 5010. "They are paying claims in a timely fashion," said Lâle White, Executive Chairman and CEO of XIFIN, Inc.

"For example, large payers, such as **Aetna**, **Cigna**, **Humana**, **Health Partners**, and most of the Blue Cross/Blue Shield plans are ready," she said. "**Availity**, which handles Florida Medicaid, and some of the clearinghouses, such as **Caparo** and **Emdeon**, are ready.

"All of the Medicare administrative carriers (MAC) are live and in production," explained White. "However, at some MACs, there remain a number of outstanding issues that are still being resolved, even though they are converted to 5010.

"On the opposite end of the spectrum, **Kansas and Missouri Blue Cross** are still in testing mode and are not ready to go live," she noted. "**GHI**, the same. **HMSA** in Hawaii is live for 5010 production but is still in testing mode for supplementary files. This means denials for providers who deal with Hawaiian payers. There are hopes that HMSA will be fully up to speed with 5010 in February."

Across the nation, it is a different story with state Medicaid programs. "A number of Medicaid payers are not ready yet," observed White. "New York Medicaid is one of them. In California, MediCal will not even begin testing its system for 5010 claims until the summer."

Roche Offers $5.7 Billion To Acquire Illumina Inc.

➤Roche wants to accelerate the transition of gene sequencing into clinical, routine diagnostics

➤➤CEO SUMMARY: Once again, Roche is hunting for gene sequencing and gene analysis technology that can support its goal of being a world leader in gene-based therapeutics and clinical lab testing that utilizes gene tests and molecular diagnostics. Last week, Roche launched a hostile stock tender offer for shares of Illumina, Inc., of San Diego, California. It is offering to pay $5.7 billion for all outstanding shares of Illumina, which rejected the proposal. Experts expect Roche will continue to pursue the acquisition of Illumina, which had revenue in 2010 of $902.7 million.

ONE BIG PHARMA and *in vitro* diagnostics (IVD) company is placing a multi-billion dollar bet that the future of lab medicine is genetic testing! That's one interpretation of the hostile take-over offer that **Roche Holding, Ltd.**, made to **Illumina, Inc.**, of San Diego, California.

On January 25, Roche offered to pay $5.7 billion for all outstanding shares of Illumina. The company makes life science tools and systems to analyze genetic variation and function. This price represented a premium of 64% over Illumina's closing stock price on December 21, the day before rumors surfaced about a potential Roche-Illumina deal. Illumina rejected the proposal. In 2010, Illumina's revenue totaled $902.7 million.

➤Holding Out for More?

As this issue of THE DARK REPORT went to press, Illumina's board was rejecting the Roche offer. Illumina says its board will issue a formal recommendation to shareholders within 10 days of the January 25 offer. Meanwhile, Roche launched its tender offer for Illumina shares.

Observers say that Roche wants to pursue ownership of Illumina because it expects the adoption of gene sequencing in clinical diagnostics to occur swiftly. Illumina holds a major market share of gene sequencing systems that are sold in research settings.

Illumina's gene sequencing technology is considered to be one of the market leaders. Adding Illumina's products to Roche's product portfolio in DNA analysis and molecular diagnostics would give the Swiss-based company a strong platform to support expanded use of gene sequencing and gene analysis by clinical labs and pathology groups.

Of course, Roche's aggressive appetite for things genetic and molecular is familiar to most pathologists and lab administrators. One example is 2007's uninvited acquisition offer made by Roche to **Ventana Medical Systems, Inc.**, in Tucson, Arizona. In early 2008, Roche agreed to pay $3.4 billion for Ventana, a company that had about $270 million in sales during 2007.

At the time, Roche said the Ventana acquisition would complement its position in both *in vitro* diagnostics (IVD) systems and oncology therapies.

But why would Roche pay $3.4 billion for Ventana, a company that had $270 million in revenue during 2007? The reason, according to *Bloomberg BusinessWeek*, is that Roche and Ventana shared an intimate understanding of the next revolution in medicine. "In the coming decade, pharmaceutical products—especially cancer drugs—will be created in tandem with diagnostic tests that tell doctors which patients are likely to benefit," reported the news magazine.

Roche Acquired BioImagene

Consider how Roche has executed this strategy. In 2010, Roche's Ventana division bought **BioImagene, Inc.**, a digital pathology company in Sunnyvale, California, that made systems for pathologists doing digital image analysis and image sharing. Ventana paid approximately $100 million for the company, which, at the time, had an estimated 100 customers worldwide.

Going back even further, it was in the 1980s when Roche launched its DNA and gene sequencing business strategy. Roche was one of the early investors in polymerase chain reaction (PCR) technology, which was developed by Kary Mullis, Ph.D., in 1983 when he worked at **Cetus Corporation**. In 1989, **Hoffmann-La Roche Inc.,** and Cetus began joint development of diagnostic applications for PCR.

PCR Patents Held By Roche

Two years later, Hoffmann-La Roche paid $300 million to formally acquire the worldwide rights and patents to PCR. From that investment, Roche has earned $2 billion in royalty patent payments from clinical laboratories and medical researchers.

THE DARK REPORT offers this history of Roche's acquisitions over the past two decades to make a point. This is a company that spent huge amounts of money back in 1901 to buy the rights to the PCR patents. Its willingness to open the checkbook and buy companies with the DNA and genetic technologies it wants is well established.

From that perspective, it may be that Illumina will end up selling to Roche—but at a much higher price than the current offer. After this happens, lab administrators should expect to see Roche to aggressively use gene sequencing technologies to create new tests for use in clinical laboratories. TDR

—By Joseph Burns

Roche Wants to Boost Its Sequencing Products

WHEN IT ANNOUNCED its intent to acquire Illumina, Inc., Roche said the proposed acquisition would strengthen its position in life sciences and diagnostics. For pathologists and lab administrators, this is Roche declaring that it is prepared to be a leader in clinical applications for gene sequencing and gene testing.

Specifically, Roche said the acquisition of Illumina and its DNA sequencing technology—when combined with Roche's existing product line—will accelerate the transition of genetic sequencing into clinical and routine diagnostics. Roche wants to strengthen its position in sequencing and microarrays to serve the growing demand for genetic and genomic solutions.

Further, as one of the world's larger pharmaceutical companies, Roche is carefully building its ability to combine diagnostic tests with pharmaceuticals. It recognizes the growing role that companion diagnostics will play in decisions about which patients qualify for specific therapeutic drugs.

To that end, Roche is telling the investment community that DNA sequencing will play a major role in helping researchers discover complex biomarkers that could become companion diagnostics and be paired with specific treatments. Illumina's technology and gene sequencing products will give Roche more capabilities in this area.

Genetic Test Update

Personalized Medicine: Meet Pathologists' New Competitors

Silicon Valley and Wall Street are joining forces to develop next-generation diagnostic technologies

By Robert L. Michel

IF THERE IS ANY SINGLE "NEXT BIG THING" that will truly revolutionize healthcare, it is likely to be personalized medicine. This approach promises to deliver improved outcomes to individual patients, while helping to control—or even reduce—the cost of care.

Central to personalized medicine will be the need for the physician to have information about the patient's DNA, RNA, and proteins. And the common expectation—at least for the foreseeable future—is that clinical labs and pathology laboratories will accept clinical specimens from the referring physician and perform these analyses.

However, such a scenario overlooks a major threat to the clinical labs and pathology groups now in operation. This threat was on public display last week at the annual **Personalized Medicine World Conference** (PMWC) that took place, appropriately enough, at the **Computer History Museum** in Mountain View, California.

Held in the heart of Silicon Valley, PMWC is a conference produced by **Silicom Ventures** and overlooked by the clinical laboratory testing industry. Over the course of two days, there were 75 presentations by healthcare leaders and business executives who are helping their organizations develop technologies and services to support personalized medicine. There were also formal presentations by 33 emerging companies that have some type of personalized medicine product or service under development.

I was one of more than 900 people in attendance. If there was one key insight which jumped out from these presentations and speeches, it had to be that Silicon Valley and Wall Street both recognize the profit potential in serving the needs of personalized medicine.

Wall Street and Silicon Valley

More importantly, these two communities are coming together. Wall Street is providing substantial capital and business expertise to a large number of high-energy, very smart scientists, entrepreneurs, and technology wonks. The common goal of these players from Silicon Valley and Wall Street is to develop the next big thing that advances personalized medicine and generates big profits.

My impression is that much of this activity is not on the radar screen of the clinical laboratory industry. But then, it is probably accurate to say that this activity is also unrecognized by most of the medical profession.

Over two days of presentations, networking, and conversations with other speakers and attendees, I came up with at least three primary insights.

First, there are really smart people developing some truly disruptive technologies. Obviously, understanding how

to sequence, analyze, and understand DNA, RNA, and molecular material is a major area of research and development.

In a similar vein, another big area of development involves how information technology (IT) can be applied. Some well-financed enterprises want to apply IT to improve existing workflow in medicine. Others want to create improved access to medical/health information or to help researchers and physicians sift through clinical data to better understand how to diagnose and treat disease.

The common goal of these players from Silicon Valley and Wall Street is to develop the next big thing that advances personalized medicine and generates big profits.

Second, some companies are taking semiconductors and related technologies and applying them to diagnostics. At PMWC, a British company called **DNAe** (*www.dnae.co.uk*) discussed its gene point-of-care testing device. It is a semiconductor chip that takes almost any DNA sample, then does prep, amplification, and the test. It requires one minute to handle, returns a result in 30 minutes, and the operator needs no advanced training.

The unique twist on this genetic POC testing device is that it uses a USB drive. This provides power to the device and allows the operator to use the computer screen and keyboard. Further, because the test is done on a semiconductor chip, the device transmits digital results.

Third, there are companies that want to use the Internet, social networking, and mobile devices to engage consumers and patients on aspects of healthcare. Think of health sites organized like **Facebook** and **MySpace** that help patients connect with other patients who also have their same disease and health condition.

One presentation was done by **PatientsLikeMe.com**. Currently, 128,990 patients have established their own page. PatientsLikeMe has structured information templates for 1,000 diseases and health conditions.

Sharing Experiences

It website states "PatientsLikeMe is committed to putting patients first. We do this by providing a better, more effective way for you to share your real-world health experiences in order to help yourself, other patients like you and organizations that focus on your conditions."

Throw HIPAA and patient privacy out the window! These patients are putting detailed medical histories on their pages. They want to learn anything they can from other patients who have the same condition.

At the same time, PatientsLikeMe.com's detailed database enables anyone to use any combination of variables to drill down and find people exactly like themselves. For patients frustrated by an unresponsive traditional medical system, PatientsLikeMe gives them an instant way to get information that is useful to them.

Two Consequences

My fourth observation—and the most important—is that much of this activity is being led by people who are outside of traditional medicine. That will have at least two consequences.

One, some developers are naïve about the need to engage established medical professionals in the design and function of their products. Two, often these developers may not fully understand the barriers to acceptance that must be addressed as they launch their products and services into the clinical marketplace. **TDR**

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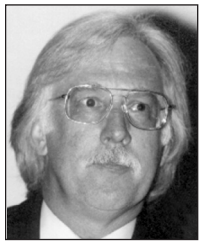
NEWSMAKER INTERVIEW



Jack Shaw

Stu Adelman

From Modest Beginnings, Two Lab Networks Find Success

"For 20 years, our regional laboratory network here in Detroit has played an important role in helping member hospital laboratories build their lab outreach programs."

—Jack Shaw, *Executive Director, Joint Venture Hospital Laboratories*

➤➤ ***CEO Summary: During the 1990s, hospital laboratories in Detroit, Michigan (1992), and Seattle, Washington (1996), banded together to form regional laboratory networks. In both networks, one primary goal was to protect and expand access to managed care patients by contracting with health insurers as a single entity that offered regional coverage. Now, almost two decades later, each regional laboratory network is prospering. In this exclusive two-part interview, THE DARK REPORT brings together the executive directors of both networks to discuss the reasons why their respective networks have lasted two decades, along with useful lessons learned about managing regional lab networks.***

Part One of Two Parts

INTRODUCTION TO INTERVIEW: One hot lab industry trend during the mid-1990s was regional laboratory networks (RLN). In many communities across the nation, local hospital laboratories decided to organize a collaborative network.

The regional laboratory network trend turned out to be relatively short-lived, with a few notable exceptions. One such exception is found in Detroit, Michigan, where **Joint Venture Hospital Laboratories** Network (JVHL) has helped its member hospitals and health systems maintain dynamic and growing laboratory outreach programs for almost two decades.

Another exception is **PACLAB Network Laboratories**, a thriving regional laboratory network based in Seattle, Washington. It was founded in 1996 and has grown into one of the larger clinical laboratory organizations in the Seattle-Tacoma metro area.

Both regional lab networks are powerhouses in their service area. For example, JVHL has 128 hospital labs in a network that covers the entire state of Michigan, and spills over into several neighboring states. It holds 23 managed care agreements covering 2.8 million members for outpatient and physician office laboratory services.

It is a similar story for PACLAB, which became operational in 1996. It combines the resources of five of the region's most established health systems and hospitals. That allowed PACLAB to form Washington's only statewide laboratory system. Like JVHL, PACLAB holds a number of important managed care contracts, covering several million lives.

Integration and shared effort is a major factor that contributes to the success of these regional laboratory networks. By integrating aspects of the lab testing services of their respective hospital laboratory members, both regional laboratory networks are able to deliver added value to physicians and payers in the community. Moreover, these added value services would be expensive and difficult for any member laboratory to offer by itself.

To unlock the secrets behind the success of these two regional laboratory networks, THE DARK REPORT recently interviewed their executive directors. It was a no-holds-barred session, full of candid insights on the challenges of operating a regional laboratory network.

Jack Shaw is the Executive Director of JVHL. He was present at the birth of this network in 1992 and has guided this organization since that time. At the time that PACLAB was formed in 1996, Stu Adelman was present. He served as PACLAB's Executive Director from that time until July 2011, when he resigned to accept an executive position at another laboratory organization in the Seattle metro.

Together, these two individuals represent 35 years of experience in managing a regional laboratory network. They carefully guided their lab networks through the tumult of the 1990s, when HMOs and full-risk, capitated contracting significantly eroded reimbursement of lab testing serv-

ices. Throughout the 2000s, both lab networks continued to evolve in response to new market developments.

In part one of this two-part interview, Adelman and Shaw discuss the ups and downs of creating a functional regional laboratory network. They reflect on the elements that contributed to the sustained financial and clinical success of their respective lab networks.

In part two of the interview, Shaw and Adelman identify the lessons learned from their combined 35 years of lab operations. They also offer candid recognition of circumstances that, if handled differently, would have increased the success of their respective regional laboratory networks. *—Editor*

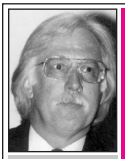
The Interview:

EDITOR: Gentlemen, each of you has unique perspectives on the management and operation of regional laboratory networks that stretches back 20 years for you, Jack; and 15 years for you, Stu. Would you start by describing the important differences between JVHL and PACLAB?

SHAW: JVHL's core membership involves five health systems in the Southeast Michigan market area that operate a total of 20 hospital laboratories. As many as 126 hospital laboratories participate in its various managed care contracts. The primary mission of JVHL is to provide access to managed care plans in this region. It handles contract negotiations and manages the relationship with each health insurance plan. JVHL receives payments from payers and disburses these receipts to the member laboratories. It also pulls together utilization and results data and other information from member labs that must be assembled and submitted to the different health plans on a regular basis.

ADELMAN: PACLAB is currently comprised of 13 hospital laboratory members. The general manager of PACLAB is **Pathology Associates Medical Laboratory** (PAML). From its inception in 1996, PACLAB's primary purpose has been to create and manage all aspects of a laboratory outreach program. PACLAB's sales reps call on office-based physicians around the campus of each member hospital laboratory to win new business. PACLAB also handles all aspects of managed care contracting for the network and its member labs. Outreach revenue is offset by the network's costs and the remaining funds are distributed regularly to the member hospitals.

EDITOR: Has PAML's role in providing management services to PACLAB given this lab network more corporate business expertise than what is available to JVHL? I know that PAML provided the working capital and management resources needed to develop standardized testing across all labs in the network, along with helping to build a single, integrated lab informatics capability.



Jack Shaw

➤"JVHL was started with limited operating capital and operates on a no-frills budget."

SHAW: That is one major difference. JVHL was started with limited operating capital and operates on a no-frills budget. Our operating budget of just over $2 million per year drives $100 million in annual healthcare spending in Michigan. We want to operate as inexpensively as possible so that every possible penny can be sent back to the hospitals participating in JVHL. By operating in this manner, we have steadily grown into a substantial business.

ADELMAN: You are correct, Jack, in that PACLAB has a much larger operating budget. We also have a unique distribution model where we pay our member

hospitals in three different ways. First there is an infrastructure-based reimbursement that reflects the operational costs incurred by each member from its participation in PACLAB. There is reimbursement for whatever a member lab puts in, including specimen processing, phlebotomists, couriers, and the like. That is about a third of PACLAB's costs and there is a percentage for margin.

EDITOR: What about the second and third source of payment to members of PACLAB?

ADELMAN: The second way is marginal test cost reimbursement. For each test that a member lab performs, it is paid based on a discounted fee schedule plus a percentage for margin. The third way involves the profit sharing portion that is returned to each PACLAB member on a regular basis. Because PACLAB operates an effective laboratory outreach program—including an ongoing and aggressive sales and marketing campaign—it incurs more administrative and operational costs than JVHL. These are significant differences that make it difficult to directly compare PACLAB and JVHL.

EDITOR: It is interesting that, whereas PACLAB operates as a consolidated and standardized lab outreach program active on all the campuses of its member hospitals, JVHL has just a few full time employees over the past 20 years and has not provided a sales force in the field to help JVHL member labs increase their share of the lab outreach market.

SHAW: That is an important distinction. JVHL never sells directly to office-based physicians. Our member hospital labs do their own outreach sales and marketing. Rather, JVHL sells its network as a single solution to health plans and managed care companies. That has always been a large part of what I do. We let each of JVHL's 128 hospitals manage their own territories by giving them the tools to service the various managed care contracts. The contracts negotiated by JVHL are door openers for the sales reps of our member labs.

EDITOR: Jack, what lessons has JVHL learned about managed care contracting with payers in Detroit and across Michigan?

SHAW: In its early years, JVHL gave its member labs a quiver full of exclusive payer contracts. Over time, we migrated away from that exclusivity strategy because we believed our member hospital labs could compete effectively against the commercial lab companies.

EDITOR: Was there any trade-off from this change in strategy?

SHAW: Yes! Once we decided JVHL did not need to have only exclusive managed care contracts on behalf of our member labs, it meant we did not have to be so willing to offer payers only substantial discounts to get contracts. We do our contract negotiations on incremental cost structures because that makes us able to compete with the commercial labs, but introducing non-exclusive contracts allowed JVLH to increase the revenue per test that it generates for the hospitals.

ADELMAN: This was done differently at PACLAB, because our network had very few contracts. In fact, the only major contract we had was with **Regence**, the Blue Cross company in Washington. Back in 1996, that was the contract that kicked PACLAB into start mode, since hospital labs believed Regence was going to accept only one bill from one provider. That motivated the members of PACLAB to get together. As PACLAB grew and evolved, it used the member labs' contracts that they had through the hospital and that hospital's billing ID number. One hospital might have had much better terms for its lab outreach program than another—but PACLAB took it all, whatever was available. It was eight hospital labs that came together in

1996 to finalize this network agreement with PACLAB that, among other things, allowed PAML to bill on their behalf.

EDITOR: Stu, your story about events in Washington in the mid-1990s is similar to what was unfolding in Detroit at about the same time. Jack, wasn't JVLH created specifically to allow its member hospital labs to participate with managed care contracts in Detroit?

SHAW: Yes. In fact, the health plan owned by four Detroit health systems was preparing to grant a sole-source lab outreach contract to a commercial lab. At the time, this health plan—rather than work with its owner hospitals' labs—said it was proceeding with its intention to issue a sole-source lab outreach contract.

EDITOR: So JVHL came together because the four health systems wanted their laboratories to continue to provide lab testing to this health plan, is that true?

SHAW: Yes. Therefore, it was necessary to form JVHL so it would look and act as a "single laboratory" across the plan's market region. JVHL would consolidate all claims submitted by the four health systems as required by this health plan and handle it as a single claims and reimbursement stream. JVHL was required to manage all operations under this contract and accept capitation (which was distributed equitably to member labs). Essentially, JVHL came into existence to look like a large commercial lab company.

EDITOR: How receptive was the health plan to this regional laboratory network strategy?

SHAW: They were willing to talk to us. We presented the regional lab network plan to this health insurer and convinced it to take a chance on us. That was a big step on the plan's part because JVHL had no history to show that it could fulfill the expectations of this payer. But we were given a one-year contract to prove ourselves. It was the jump start to JVHL.

EDITOR: How did this first managed care contract help JVHL?

SHAW: By the end of the first year, it was clear that the regional laboratory network was functioning and that other hospital laboratories were interested in joining JVHL. That was when we developed a strategy to compete effectively against the commercial labs in our market. Within four years, we had contracts with four other health plans.

EDITOR: What came next?

SHAW: In 2000, we had the opportunity to enter into a statewide contract. But to do that, it was necessary for JVHL to expand to 100 or more hospitals so that our network would have the access required by this health insurer. Once we had a statewide network, we started filling in the gaps. Today, JVHL holds 123 contracts with 128 hospitals. JVHL restricts its managed care contracts only to the contracts that hospitals can't negotiate for themselves. We have local and regional contracts, and we have contracts with all the national payers in our market, including **Cigna**, **Aetna**, **and UnitedHealthcare**.

EDITOR: In addition to the primary function of managed care contracting, what else has JVHL done?

SHAW: Creating a statewide service network was a major milestone. JVHL is now actively building an interfaced informatics platform so it can move into what we call the information decade of our existence.

EDITOR: Stu, are there similarities in the PACLAB story, given what happened in Washington when PACLAB obtained a contract with Regence Blue Cross at the time of PACLAB's founding in 1996?

ADELMAN: Having an important managed care contract was a jumpstart for PACLAB as well. PACLAB also benefited from PAML's business and sales expertise at the time it was founded. PAML had a professional sales team that, from the

outset, helped to drive the outreach success of PACLAB.

EDITOR: Isn't there a bit more to this story of PACLAB's launch?

ADELMAN: That is true. PAML is owned by **Providence Health** and the Providence hospitals agreed not to compete in Western Washington—meaning the Seattle/Tacoma area. That would be PACLAB's turf. By offering PAML's sales team and billing resources to PACLAB, the Providence hospitals took a significant step in helping PACLAB launch operations and quickly become profitable.

EDITOR: You mention that PACLAB had access to PAML's billing expertise. Why was that useful?

Stu Adelman

"That success allowed us to add additional hospitals over time because the hospital administrators saw that lab outreach was profitable. It put their lab in a completely different focus."

ADELMAN: In general, hospitals—at least those in Washington—do a poor job of collecting the numerous small bills that are a large part of outreach lab test billing and collections. Basically, hospital billing departments tend to write off those lab bills. By using PAML's billing department, PACLAB was able to collect a high proportion of those small lab test bills.

EDITOR: What other factors came into play?

ADELMAN: There was another problem that PAML helped PACLAB overcome. Not surprisingly, at the beginning, members were a bit wary of each other. There was also a thought that, maybe PAML, as PACLAB's general partner, eventually wanted to take over their lab businesses. However, over time, PAML's CEO, Thomas Tiffany, Ph.D., consistently acted in the best interest of the PACLAB network, even leaving money on the table at times. That was significant in those early days because people saw how Dr. Tiffany put the network first and trust started to grow.

EDITOR: How long did it take for PACLAB to produce revenue and positive operating margins?

ADELMAN: That was the other factor that helped establish trust among the PACLAB members and PAML. Even in the first year, the PACLAB hospitals had significant cash distributions from our regional laboratory network. In other words, after those cash distributions in the first year, the member hospital CFOs saw that laboratory outreach testing could be profitable when it was run and billed professionally. With that, each member's hospital laboratory went from being an expense center to being a revenue generator.

EDITOR: What was the next chapter in the PACLAB growth story?

ADELMAN: Not surprisingly, the financial success of PACLAB was quickly noticed throughout Seattle. That success allowed us to add additional hospitals over time because the hospital administrators saw that lab outreach was profitable. It put their lab in a completely different focus.

EDITOR: How do you mean? What changed within these hospitals?

ADELMAN: Once hospital administration saw the financial and clinical benefits of their laboratory and its role within PACLAB, thereafter, when the lab needed instrumentation or staff, they got it. Having PACLAB checks come in every month changed the whole philosophy of how the hospitals viewed their labs.

EDITOR: Did the governance structure of PACLAB play a role in this, as well?

ADELMAN: Definitely. PACLAB's structure directly contributed to our success. At each member hospital, the CEO, CFO, and the lab administrator were engaged in the entire operation. Because

these leaders helped to make decisions about PACLAB's strategy and business operation, they were part of the process that led to our success.

EDITOR: This is a key point, since many pathologists and clinical lab administrators regularly grumble about the fact that the administration of their parent hospital or health system does not recognize the value of the laboratory. My question for Jack is this. How did JVHL educate and involve the administration of its member hospitals?

SHAW: The governance and operation of JVHL was and is primarily supported by the administrative directors of labs or—one step up—the VP for ancillary services. JVHL learned early that it was important to have a pathologist from its core hospitals at the table. While pathologists may not always have the business acumen of the hospital administrators, they add important insight and input. Further, it has been a pathologist who has served as chair of JVHL's Executive Committee for the past 15 years and they have been good businessmen.

EDITOR: Were pathologists in Detroit supportive of JVHL as a clinical lab testing network?

SHAW: That answer is an easy "yes!" Early on, it was the pathologists who helped convince the hospital administrators that there was a good business opportunity in lab outreach.

ADELMAN: I would like to ask Jack about JVHL's approach toward building the lab outreach business of its member hospitals. Was there a specific strategy and how did it differ from our PACLAB model, which used sales reps employed and managed by PACLAB to win new clients for the member hospitals?

SHAW: That is a good question and strikes to the heart of our different strategy. In contrast to PACLAB, JVHL did not try to assume responsibility for the sales and marketing of a member hospitals lab outreach business. JVHL concentrated on pieces of the lab outreach business with which we believed the hospitals did not historically have success. Negotiating and servicing managed care lab outreach contracts was our primary focus. JVHL does all the managed care contract billing and has developed a very sophisticated reimbursement operation to support the contracts.

EDITOR: Does JVHL handle the entire lab outreach billing for member hospitals, or just the managed care contract billing?

SHAW: While JVHL could handle the outreach billing operations of our member our member hospitals (and we might be able to improve on their collection experience—particularly for the smaller claims), JVHL concentrates on the billing of its managed care contracts' claims.

EDITOR: What type of claims volume does JVHL handle currently?

SHAW: At this time, we handle about 400,000 claims a month and each claim is for a managed care contract that is held by JVHL. This claims volume represents about 30% to 35% of the total lab outreach business of our member hospitals. That statistic shows the importance of JVHL's managed care contract strategy in aiding our members to build the size and revenue volume of their individual lab outreach programs.

EDITOR: Jack and Stu, we will need to stop here. Thank you for sharing the insights about the creation and the strategic goals of your regional laboratory networks. In part two of this interview, we will explore the insights and management lessons learned that other hospital and health system labs can apply to their own outreach testing programs. TDR

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GHSU Graduates Med Techs Using Distance Training

Medical Laboratory Scientist training program helps laboratories to recruit and to train MLSs

CEO SUMMARY: Many clinical labs experiencing a shortage of trained medical laboratory scientists (MLS) in their city continue to overlook how the use of distance training programs could help them attract and retain top-performers. Leaders of the clinical laboratory scientist (CLS) distance training program at Georgia Health Sciences University (GHSU) say distance students are enthusiastic and learn just as much as their in-classroom peers. It is one reason why GHSU has added an MLS masters distance program.

IN MANY COMMUNITIES, clinical laboratories lament the shortage of skilled medical laboratory scientists (MLS) and clinical laboratory scientists (CLS). Yet these same labs seem to overlook the opportunity to use distance training programs as a useful way to recruit and retain more MLSs.

To learn about the value that MLS/CLS distance learning programs can provide, THE DARK REPORT caught up with Barbara L. Russell, Ed.D., MLS (ASCP), SH (ASCP). Russell is Associate Professor and Program Director of the Program of Clinical Laboratory Science (CLS) at **Georgia Health Sciences University** (GHSU) in Augusta, Georgia.

GHSU (formerly known as the Medical College of Georgia), operates one of the nation's oldest MLS/CLS training programs. It was established in 1938.

In 1993, a distance learning program for students who were already medical laboratory technicians (MLT) was instituted. Then, in 2002, the distance learning program for students who had no laboratory training was started. "Distance learning at GHSU, has been a great success," stated Russell. "Since 2002, 62 distance learning students have graduated from this CLS program.

"Our distance learning program curriculum is identical to the campus-based learning program, except where the student laboratories are performed," she noted. "While on-campus students perform this activity in campus laboratories, the distance learning students—like those in Oregon and others outside the Augusta area—perform their laboratories at clinical affiliates, such as **PeaceHealth Laboratories** in Springfield, Oregon, and **Good Samaritan Regional Medical Center** in Corvallis." *(See TDR, January 9, 2012.)*

Mobile Laboratory

GHSU recently beefed up its distance learning program to make it easier for distance learning students in Georgia to complete the laboratory requirements. The innovation is a fully-equipped, state-of-the art mobile laboratory.

This 11-by-53 foot mobile lab was introduced in the fall of 2010. It is parked

in Lawrenceville, Georgia, at **Gwinnett Health System Medical Center** and is used by distance learning students in the Atlanta metro area. These students perform their student laboratories in the mobile laboratory, under the direction of a GHSU faculty and at the sites of their internships, which are at affiliated clinics in Atlanta.

Gregory C. Passmore, Ph.D., CNMT, (certified nuclear medical technologist) is the Interim Department Chair of Medical Laboratory, Imaging, and Radiologic Sciences at GHSU. He stated that, "This mobile laboratory makes it possible for us to provide a convenient hands-on learning environment for GHSU's distance learning students in the Atlanta metropolitan area. These CLS students need access to a medical laboratory for portions of their online programs.

Master of Health Science

"Another enhancement to the distance learning opportunities for clinical laboratory professionals is an entry-level graduate CLS degree: the Master of Health Science in CLS (MHS-CLS)," said Passmore. "This is for students who have a baccalaureate degree and want to obtain their CLS degree. The curriculum has all of the content included in the bachelor of science in CLS (BS-CLS) degree. It also provides advanced competencies in each content area, advanced practice courses, and research courses that culminate in a capstone evidence-based research project."

"Our MHS-CLS program is offered through distance learning and is identical to the campus program here at GHSU," added Passmore. "Classes are built upon the same in-class lectures that professors give to students in the GHSU residency program. These lectures and instruction modules are uploaded to the distance learning program's Web content.

"Online distance learning attracts students with an independent learning style," added Passmore. "These classes are asynchronous and are student-centered. Educational resources that support this learning include email, electronic mailing lists, threaded conferencing systems, online discussion boards, wikis, blogs, text and voice chat, telephone conversations, videoconferencing, and even meetings in virtual spaces that can facilitate sharing among the online classroom's network of students at any time."

Distance Learning

Lab administrators and pathologists will be interested to know that distance learning is proving to be equally effective as the more traditional classroom approach. "Studies comparing online and classroom education outcomes have not found much difference between the two," affirmed Passmore.

"Moreover, although some distance learning students voice the concern that they miss the person-to-person interactions of a traditional classroom, the access they have to faculty and other students via the methods I mentioned earlier makes up for that," he said.

Lab educators at GHSU have not overlooked the rapid growth in molecular diagnostics and genetic testing. "Both the BS-CLS and MHS-CLS distance and campus students are exposed to molecular techniques through didactic, student laboratories, and internship courses," noted Russell.

"In addition, the MHS-CLS program has a separate six-week Clinical Molecular Methods Internship course," concluded Russell. "In this course, students learn advanced techniques in molecular testing. They develop skills that could be used in research and development (e.g., such as how to design polymerase chain reaction based assays to detect DNA sequences of choice)." TDR

—By Carren Bersch

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It's a sign of the times and a warning to clinical labs and lab industry vendors. Money is short at some community hospitals—meaning bills are going unpaid. In Birmingham, Alabama, the *Birmingham News* reported that **Cooper Green Mercy Hospital** is $1 million behind in its bills. Among the creditors mentioned were **Beckman Coulter Corporation** and the **University of Alabama at Birmingham** (possibly for reference laboratory testing services). The *Birmingham News* stated that the accounts payable list for medical and laboratory accounts include "unpaid bills for hematology supplies; chemistry supplies; blood supplies and a number of other areas that range in amounts [to individual vendors] from $461 to $365,961, according to the records."

MORE ON: *Cooper Green Mercy Hospital*

This 121-bed community hospital is getting less funding from the Jefferson County Commission. For the past six months, it has only been able to draw funds from the county's indigent care fund, whereas earlier it could also get money from the county's general fund. Jefferson County was forced into a high-profile bankruptcy in November 2011. The county listed $4.2 billion in debt and is the largest municipal bankruptcy ever filed in the United States. Financial experts predict that more cash-strapped municipalities may be forced to take similar steps in coming years. That will directly affect healthcare providers, including laboratories, located in these communities.

CORRECTION

The December 19, 2011, issue of THE DARK REPORT, discussed the ISO 15189 accreditation of the **Spectra Laboratories, Inc.**, lab facility in Milpitas, California. On page 18, it was stated that both Spectra Lab facilities—in Milpitas and in Rockleigh New Jersey—were also accredited by **The Joint Commission**. This should be corrected to state that only the Milpitas lab has accreditation from The Joint Commission.

LABCORP HELPS ABU DHABI BUILD REFERENCE LAB

Abu Dhabi opened its new **National Reference Laboratory** on January 22, 2012. The press release for this opening stated that the new facility was "a partnership between **Mubadala Healthcare** and the **Laboratory Corporation of America**." The arrangement is another example of the globalization of clinical laboratory testing.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how the **Centers for Medicare and Medicaid** (CMS) services will make its Medicare database available to the public. This will make it possible to see the outcomes of hospitals and individual doctors for the first time.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 20, 2012.

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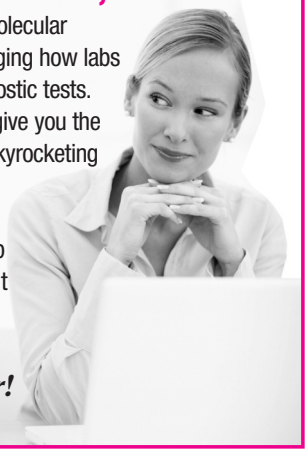
*Preview–**Matthew Zubiller** of McKesson ADM on...*

Getting Paid for Molecular Diagnostics: Payer Pre-Authorization, Z-Codes, & More



Is your lab ready to say "good-bye" to code stacking for molecular diagnostic tests? Government and private payers are changing how labs must code and bill for genetic assays and molecular diagnostic tests. Zubiller is on the front line in this transformation and he'll give you the behind-the-scenes story about payer frustration with the skyrocketing costs of genetic testing and molecular diagnostics. You'll learn about payer pre-authorization, why one Medicare carrier decided to use Z-codes, and practical steps your lab can take to ensure accurate settlement and timely payment for your genetic and molecular test claims. Register today and ensure your place at this important event!

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UPCOMING...

- ***Ultimate Lab Consolidation Play: Why Wall Street Believes LabCorp Could Acquire Quest Diagnostics.***
- ***How the QMS of ISO 15189 Helped 500-Bed Hospital Lab Achieve Continuous Improvement in Test TAT, Accuracy.***
- ***Practical Successes in Specimen Processing, Pre-Analytical: New Ways to Benefit From Existing Lab Automation.***

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