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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

Rural Hospital Labs and Their Lab Directors

FROM TWO DIFFERENT STATES, WE PRESENT INTELLIGENCE BRIEFINGS that have a common element: laboratories in many rural hospitals are struggling. We consider these stories, when taken together, to be persuasive evidence that some significant number of rural hospital laboratories are experiencing ongoing erosion of their financial stability.

First, you will read about the closure of 37-bed **E.J. Noble Hospital** in Gouverneur, New York. Alerted to deficiencies in the laboratory by the laboratory director who was terminating his contract for this reason, New York state health department officials inspected the lab and later suspended the lab's license. In response to that action, hospital administrators closed the hospital last month and it may reopen soon. *(See pages 3-10.)*

Next, we were following up the intriguing story that a pathology supergroup in Shreveport, Louisiana, was building a substantial business in laboratory consulting when we learned something interesting. Requests from rural hospitals for help to maintain the CLIA compliance of their labs is one of the fastest-growing areas of **Pathology Resource Network**, the lab management company established by the 26 pathologists of **Delta Pathology Group, LLC**. *(See pages 11-14.)*

Consider these two developments in tandem with the action taken by New York lab regulators earlier this year to close the laboratory of 173-bed **Peninsula Hospital** in the Far Rockaway section of Queens, New York. In that case, NYSDOH officials found the financially-struggling hospital had serious deficiencies in its lab operations. *(See TDR, March 12, 2012.)*

In my opinion, we are seeing the first wave of hospitals forced to close because ongoing financial problems caused their administrators to starve their institutions' laboratories of money needed to maintain lab testing activities at a compliant level. It is known that many hundreds of hospitals across the nation don't generate enough revenue from patient services to cover their operational costs. Thus, you should expect to see more examples of hospitals forced to close because regulators found serious deficiencies in their laboratories.

For that reason, pathologists who serve as laboratory directors and are on the license for rural and community hospital labs may want to pay much closer attention to the effect that shrinking hospital lab budgets have on the ability of their laboratories to operate without serious deficiencies. TDR

NY Hospital Closed Due To Deficiencies in Lab

It's every laboratory director's nightmare: not enough staff, vendors owed money, and errors

CEO SUMMARY: Lab executives and pathologists have long read about the deteriorating finances at many rural hospitals, along with their struggles to recruit and retain enough skilled laboratory staff. Now the closure of the laboratory at 37-bed E.J. Noble Hospital in Gouverneur, New York, can be considered a sign that these long-discussed trends are becoming reality. In response to the lab's problems, the laboratory director resigned and notified state officials, who closed the lab after an inspection.

In upstate New York, state health officials recently ordered a rural hospital to close its laboratory due to operational deficiencies and at least one patient error involving blood products. In response to the closure of the lab, the hospital ceased accepting patients and shut down.

In the normal course of events, this story attracted little attention in the news media and these events are unknown to pathologists and clinical laboratory professionals. After all, what can be significant about the closure of a financially-troubled, 37-bed hospital located in a rather remote rural town of 3,938 people that is located in a thinly-populated region just 40 miles from the Canadian border?

For both the clinical laboratory industry and the pathology profession, there is much national significance to this story, a conclusion which may surprise many in the lab industry. The Dark Report believes that the problems of the clinical laboratory at the non-profit **E.J. Noble Hospital** in Gouverneur, New York, are the tip of a much larger iceberg.

Essentially, what happened at E.J. Noble Hospital may be a story that is about to be repeated at other rural hospitals throughout the nation, and even at other financially-struggling community hospitals in larger towns and cities.

That is because the laboratory at E.J. Noble Hospital appears to represent the "perfect storm" where several long-predicted trends converged at the same moment in time. These trends include acute lab staffing shortages, deteriorating hospital finances, expensive clinical lab technology, heightened legal risk for

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pathologists serving as laboratory directors, and deteriorating lab reimbursement.

Ask yourself this: is your laboratory or its parent hospital or health system experiencing any two of the above listed trends and issues? If the answer is "yes," then the reasons why the **New York State Department of Health** (NYSDOH) closed the clinical laboratory of E.J. Noble Hospital on September 28, 2012, may be instructive as to how ongoing legal risks and levels of compliance exposure may be intensifying within your own lab and hospital organization.

Closure Of Noble Hospital

A basic understanding of why problems in the laboratory contributed to the closure of E.J. Noble Hospital can be found in press accounts and from officials of the NYSDOH. THE DARK REPORT presents this information on pages 6-8.

Two issues seem to dominate this case. First, the hospital was struggling to hire and retain the minimum number of medical technologists (MT) and lab scientists required to operate the laboratory with acceptable quality and safety.

Second, the hospital's weak financial condition directly contributed to the lab's problems. NYSDOH officials noted that, because vendors were owed money by the hospital, vendors were withholding shipments of reagents to the lab. In turn, that meant Noble's lab was unable "to perform critical testing due to lack of reagents."

Absolute Shortage of MTs

It is common knowledge across the clinical laboratory industry that there is an absolute shortage of medical technologists and other laboratory scientists. The inability of E.J. Noble Hospital to recruit and retain the minimum number of MTs and trained staff it needed can be considered an early warning. It is evidence that the lab industry's long-discussed manpower shortage is now poised to become reality.

Further, the report of the NYSDOH regulators after their inspection of the Noble Hospital lab supports this conclusion. The regulators determined that the combination of inadequate staff in the laboratory and poor finances of the hospital were reasons why this hospital laboratory was unable to sustain an acceptable quality of lab testing services.

In fact, this situation caused the laboratory director to terminate services with the hospital and notify the New York State Department of Health of that fact. With this notification from the former laboratory director, the NYSDOH also received a copy of the termination letter that had been sent to Noble Hospital's administrators.

It is this aspect of the Noble Hospital case that should catch the serious attention of every laboratory director of a CLIA-licensed lab. In a true sense, this laboratory director was the "whistleblower" who triggered the NYSDOH inspection of the Noble Hospital laboratory on August 25, 2012.

Lab Deficiencies

Within four weeks of this inspection, the NYSDOH determined that the hospital was unable to correct the lab's deficiencies. It was on September 28 that state regulators revoked the lab's license, causing the hospital to shut down. As of last Friday, NYSDOH lifted that order and the hospital is to reopen with a limited lab test menu.

THE DARK REPORT believes these events must be interpreted within the framework of the well-accepted laboratory trends mentioned earlier. The shortage of med techs has been visible in many regions of the United States for two decades now.

"Recruiting medical technicians is a real challenge," said Noble Hospital administrator Charles B. Conole to a local newspaper. "There are no medical technician [medical technologist] schools in Northern New York."

At the same time, the deterioration of hospital finances is well-documented. Longtime clients and readers will recall

THE DARK REPORT story titled "New Report Says Half Nation's Hospitals Have Financial Woes." *(See TDR, May 26, 2008.)*

At that time, the healthcare consulting firm of **Alvarez & Marsal, LLC**, studied the financial operations of 3,861 of the 4,900 acute-care hospitals operating in the United States. Out of the total 3,861 hospitals studied, Alvarez &Marsal said 2,044 don't make a profit on patient care! It also noted that 744 hospitals in the study earn so little that they cannot fund day-to-day operations, make needed repairs, or support basic capital expenditures.

We are now almost five years further down the path of deteriorating hospital finances—with significant cuts in Medicare reimbursement still to come. It is reasonable to assume that the problems that caused the closure of E.J. Noble Hospital will be seen in a growing number of other hospitals.

These circumstances predict a tougher future for lab administrators as well as the laboratory directors who are on the lab's CLIA license. On one hand, these lab leaders will be required to sustain a compliant and high quality laboratory with shrinking resources. That means reduced budgets from the parent hospitals, more difficulties in recruiting adequate numbers of med techs and skilled lab staff, and the challenge of acquiring more expensive and complex lab testing equipment.

Ethical Dilemma In The Lab

On the other hand, in situations where the hospital is financially strapped, lab administrators and laboratory directors will face the very real ethical dilemma of how to handle situations similar to E.J. Noble Hospital. In that case, hospital administration was unwilling or unable to provide the leadership and the financial resources the laboratory needed to correct ongoing deficiencies and restore compliance to the acceptable level.

That created the moment when the laboratory director decided the right thing to do was to terminate his service contract with the hospital. Also, as the law requires, the laboratory director notified the proper lab authorities in his state about these issues.

Every lab administrator and laboratory director—particularly those working in hospital laboratories where such deficiencies are already visible—should study the public facts of the E.J. Noble Hospital laboratory closure. In the pages that follow, THE DARK REPORT provides information about these events, as well as an overview of these issues by an experienced attorney. TDR

Peninsula Hospital Closed Because of Lab Problems

IT WAS IN APRIL OF THIS YEAR when the New York State Department of Health revoked the certificate of another hospital laboratory, an action that led to the closure of the hospital.

This time it was the laboratory of the 173-bed hospital **Peninsula Hospital**, located in the Far Rockaway section of the Borough of Queens. The department sent inspectors to the lab on February 20 and 21. Days later, on February 23, the department issued the order to close the laboratory for 30 days. *(See TDR, March 12, 2012.)*

This action was taken after a NYSDOH inspection found that the hospital laboratory "failed to meet accepted standards, which put patient safety at risk." In its report, the NYSDOH noted that some reagents were outdated and that a lack of other reagents meant the lab was unable to perform certain types of tests. Another issue was the lack of proper supervision across all shifts and in different departments of the laboratory.

As in the case of E.J. Noble Hospital, it appears that the poor financial condition at Peninsula Hospital played a significant role in the inadequate lab staffing and problems with maintaining inventories of essential reagents and laboratory supplies.

Lab Director Blows Whistle, NY Closes Hospital Lab

State cites numerous problems, including a blood transfusion error and wrong PT results

CEO SUMMARY: Unable to overcome problems at a rural hospital laboratory caused by the parent hospital's financial problems and the inability of the hospital to recruit adequate numbers of lab staff, the laboratory director terminated his agreement with the hospital and notified the New York State Department of Health about the situation. Alerted by this notice, NY state lab regulators inspected the hospital lab and found additional deficiencies. When the hospital failed to keep the terms of a corrective agreement, the state revoked the lab's license and the hospital closed.

Residents of rural Gouverneur, New York, have been without a hospital following an order from the **New York State Department of Health** (NYSDOH) to shut down the local hospital's clinical laboratory last month. The severe regulatory action was taken in response to serious deficiencies found at the hospital's lab.

Events leading up to the revocation of the clinical laboratory's license at 37-bed **E.J. Noble Hospital** tell a fascinating story. These events also provide a timely case study of how widespread lab industry trends are combining in ways that increase the financial liability, legal risk, and compliance exposure of any pathologist serving as director of a CLIA-licensed medical laboratory that is part of a hospital or health system.

Here are the facts: the hospital was shut down on September 28 after officials from the NYSDOH found serious deficiencies in the hospital's clinical laboratory. State officials listed 14 deficiencies. For example, state inspectors found that the laboratory was using expired reagents for testing and was storing human specimens and reagents in a freezer with plasma for transfusion, which could result in contamination of the blood supply.

Most serious was the transfusion of the incorrect blood type as the result of a laboratory testing error. State inspectors found that lab personnel had switched samples while doing testing. The lab also failed to pass a required proficiency test, and again this error resulted from switching samples, state officials said.

Given Incorrect Blood Type

The *Watertown Daily Times* reported that the patient who was transfused with the incorrect blood type has since died and the family is considering a lawsuit against the hospital. The patient had lung cancer and had been transferred to another hospital in Syracuse. It was at this facility that the patient learned he had been given the wrong type of blood at E.J. Noble Hospital.

These actions represent a sentinel event for the laboratory industry for two reasons. The first involves the consequences at a lab operated by an inadequate number of qual-

ified staff. The second, most interestingly, is the departure of the laboratory director in response to the under-staffing situation, along with other relevant issues.

Because of its rural location, it appears that Noble hospital was finding it very difficult to hire and retain adequate numbers of the medical technologists and other skilled lab scientists needed to properly operate the laboratory. Administrators at E.J. Noble Hospital told the local newspaper that the hospital had a loss at the end of the most recent fiscal year as a result of losing a managed care contract.

Notified State of Termination

Second, the pathology group that provided the laboratory director named on the lab's CLIA license terminated its service contract with Noble Hospital. It then notified the NYSDOH of this termination, along with the specific reasons why it had taken this action.

ClearPath Diagnostics, Inc., of Syracuse, New York, had the laboratory management agreement with E.J. Noble Hospital. Pathologist Kenneth B. Strumpf, M.D., a partner at ClearPath, served as E.J. Noble's laboratory director.

It was August 25 when state officials inspected the laboratory after getting a copy of a letter that Michael Warner, Chief Operating Officer of ClearPath Diagnostics, had sent to the administrator of E.J. Noble Hospital. The letter from ClearPath to E.J. Noble stated that it was ending its relationship with E.J. Noble and that Strumpf would no longer serve as laboratory director, state officials said.

State Officials Cite Problems

In its letter to E.J. Noble, the NYSDOH explained numerous and serious concerns that ClearPath had with operation of the clinical lab. These reasons were described in an "Order for Summary Action" that state officials said the NYSDOH issued on September 28. The order cited the following problems, state officials said:

1. *The laboratory's inability to obtain reagents due to the vendor credit hold for nonpayment of bills;*
2. *The laboratory's inability to perform critical testing due to lack of reagents;*
3. *The laboratory's inadequate staffing, which placed patients at risk and required staff to work excessive overtime, including double shifts;*

E.J. Hospital Laboratory Did Have Corrective Plan

OFFICIALS AT E.J. NOBLE HOSPITAL had an opportunity to correct deficiencies in the laboratory. But the effort fell short.

As a result of the inspection and the blood transfusion error, regulators from the New York State Department of Health worked out an agreement with hospital administrators. The hospital was to reduce the lab's test menu to concentrate its resources on tests required to continue operation of the emergency department and to manage acute care patients.

As part of the agreement, the hospital also agreed to end all blood bank activities, except to store O negative blood for emergencies and to cancel all elective surgeries and transfer patients who need transfusions to other facilities. According to state officials, ambulances could no longer bring patients to the ER, and physicians could not refer patients to the facility.

However, by the end of September, state officials found that the lab reported proficiency testing results inaccurately, again because of switched samples, state officials said. That spurred state officials to revoke the hospital lab's license. Following that decision, Dr. Timothy J. Monroe, a veterinarian who serves as president of the hospital's board of directors, told the Watertown newspaper that state officials considered the PT failure to be "the straw that broke the camel's back."

4. *The laboratory supervisor spent excessive time performing testing, preventing her from performing supervisory duties;*
5. *The laboratory's failure to address deficiencies cited during previous surveys due to understaffing;*
6. *The laboratory's inability to revise standard operating procedures in a timely manner due to understaffing;*
7. *The frequent turnover of laboratory supervisors due to the lack of support from E.J. Noble's administration; and,*
8. *The general lack of responsiveness from E.J. Noble's administration to laboratory issues and concerns.*

When contacted by THE DARK REPORT, executives of ClearPath Diagnostics declined to comment about the letter or these events.

In the state inspection of the laboratory on August 25, state officials said they substantiated all the allegations in the letter from Warner. State lab inspectors identified 14 deficiencies and other unsafe practices, state officials said. Within two weeks, more problems surfaced at Noble Hospital's laboratory.

Samples Switched At Testing

On September 7, state officials learned about the blood transfusion error. The patient had presented at the hospital's emergency department and was transfused with the incorrect blood type as a result of a laboratory testing error, state officials said. After an investigation, state officials said they discovered that the laboratory had switched samples while performing testing.

As a result of the inspection and the blood transfusion error, state officials worked out an agreement with hospital administrators. The lab would reduce its test menu to concentrate its resources on tests required to continue operation of the emergency department and to manage acute care patients.

The basic elements of the agreement between NYSDOH and E.J. Noble Hospital are presented in the sidebar on page 7. Under this agreement, the hospital could continue to provide most of its clinical services while it worked to fix the problems identified in the operation of its laboratory.

More Errors With PT Tests

By the end of the month, state officials found that the lab reported PT results inaccurately, again because of switched samples, said state lab regulators. On September 28, therefore, state officials declared that, despite efforts to correct the deficiencies, the continued operation of the laboratory posed an imminent threat to the public health, safety and welfare. As a result, the laboratory permit was suspended for 30 days while the hospital corrected the deficiencies, state officials said.

In response to the state's suspension of the laboratory permit, hospital administrators closed the hospital. On October 26, state officials lifted the lab suspension order. In collaboration with another hospital, Noble Hospital will reopen on Monday, October 29 with a limited menu of laboratory tests, state officials said.

THE DARK REPORT observes that the situation involving E.J. Noble is similar to what happened to **Peninsula Hospital** in the Far Rockaway section of Queens, New York, earlier this year. In that case, NYSDOH officials found a facility struggling financially that had deficiencies in its lab operations. State officials shut down the lab and forced the hospital to transfer patients elsewhere.

What is different in the Noble Hospital case is that the laboratory director resigned because deficiencies went uncorrected by hospital administration, and this former lab director notified state regulators about these problems. These developments should be studied by laboratory directors in other CLIA-licensed labs, since they demonstrate how concepts of legal liability can evolve due to contemporary events. TDR

—By Joseph Burns

NY Lab Director Resigns, Cites Lack of Support

Action in response to ongoing lab problems provides case study for other CLIA lab directors

CEO SUMMARY: When the lab director resigned from his post at a clinical lab in a hospital in rural New York, the resignation letter was sent to the hospital administration and copy went to the New York State Department of Health. In the letter, the lab director outlined eight reasons for tendering his resignation. A lawyer who reviewed the facts in this case explained that the most significant of the eight reasons for resignation was the hospital administration's lack of support for correcting the lab's deficiencies.

IT WAS A LETTER OF RESIGNATION by the hospital's laboratory director that set off the chain of events that led to last month's closure of **E.J. Noble Hospital** in Gouverneur, New York, by officials of the New York State Department of Health (NYSDOH).

It is a rare occurrence for the laboratory director of a hospital to become, in effect, a whistleblower and alert clinical laboratory regulators about serious deficiencies in the laboratory. To understand the ramifications of this development, THE DARK REPORT asked Peter Kazon, a lawyer with **Alston + Bird**, a law firm in Washington, D.C., to review the published reports of the case. Kazon is not representing any principals in this case.

Kazon advises clinical laboratories and diagnostic companies on regulatory and compliance matters and is an expert in the Clinical Laboratory Improvement Amendments (CLIA), which govern laboratory operations. The New York State Department of Health regulations governing laboratory operations are similar to those of CLIA.

Kazon's observations are based on the news accounts of the closure of E.J. Noble Hospital, and the steps the NYSDOH took on September 28, 2012. The previous story on pages 6-8 provided the facts of this case and the role of **ClearPath Diagnostics, LLC**, of Syracuse, as the contracted entity which provided the services of pathologist Kenneth Strumpf, M.D., as laboratory director at E.J. Noble Hospital

Unusual Circumstances

"It would take some very unusual circumstances to cause a laboratory director to resign and provide notice to state regulators of the resignation," stated Kazon. "The case raises many issues for lab directors to consider.

"The most important issue is always whether the tests are being done accurately," Kazon said. "If tests are inaccurate, there are definite steps to take under CLIA. But the bigger issue involves the possibility of causing patient harm.

"If the lab makes a mistake and gives someone an incorrect test result that harms a patient, then the facility could be

liable in a lawsuit," he explained. "A lawsuit could be a possibility in the E.J. Noble case because there are claims about potential harm from a blood transfusion.

"But every lab deficiency needs to be addressed," continued Kazon. "Under CLIA, any lab that has problems needs to put a corrective action policy in place and follow that policy so that it can ensure that it is producing accurate and reliable tests and reports. The laboratory director has responsibility to ensure that the lab's correction action policy is followed.

Escalating Steps to Follow

"Each situation is different, of course, but there are escalating steps to follow," he said. "If the laboratory director can't get the money from the hospital to buy reagents, he or she has to stop testing and identify the corrective steps.

"As laboratory director, if you find yourself in this situation, go to the hospital administration and explain the problem," Kazon explained. "Document any and all steps. Be diligent about keeping records of email and other correspondence with the administration.

"If the hospital administration is intransigent and won't do what is needed to eliminate lab deficiencies, then, as laboratory director, you may have no choice," advised Kazon. "You may have to go to the state or CLIA regulators. Hopefully, that would always be the last resort.

Mistakes In Lab Test Results

"However, if uncorrected issues in the lab were to cause the lab director to terminate the relationship, that laboratory director cannot just walk away if inaccurate results went out the door," he added. "At a minimum, the laboratory director should see that the patients or physicians are notified that there were mistakes in the lab test results and report these problems to state officials or CLIA or both.

"Having said all that, I don't believe the E.J. Noble Hospital case will affect labs in other states," observed Kazon. "In New York, it may cause the NYSDOH to be more vigilant and it is certainly a lesson case for lab directors in every state. There is clearly more risk when serving as the laboratory directory for a laboratory that is in a financially-strapped hospital.

"The E.J. Noble case shows us how, when hospital and lab reimbursement declines, cost pressures may make it harder for labs in these financially-struggling hospitals to complete all the quality assurance steps they are required to follow," noted Kazon. "The problem is that failure to follow QA steps will not be a valid excuse for any enforcement agency. That means laboratory directors may need to be more vigilant and resourceful.

"One significant problem cited in the letter was the frequent turnover of lab supervisors due to a lack of support by Noble hospital's administration and a general lack of responsiveness from administration to laboratory issues and concerns," he commented.

When It's Time To Resign

"Those two complaints—a lack of support and a lack of responsiveness from administration—show that the laboratory director was not getting what he needed to operate the lab correctly," he said. "No wonder this laboratory director felt the need to resign."

Across the United States, a significant number of rural hospitals and community hospitals are reporting financial losses. Like E.J. Noble Hospital, these hospitals are more likely to shrink the budgets of their laboratories, starving these labs of the resources they need to retain adequate numbers of med techs, purchase reagents and consumables, and comply fully with CLIA and other regulatory requirements. Thus, it is likely that the lab industry will see more laboratory directors turn "whistleblowers" for all the appropriate reasons. TDR

—By Joseph Burns

Contact Peter Kazon at 202-239-3334 or peter.kazon@alston.com.

Louisiana Pathologists 'Moonlight' as Consultants

Group formed a lab consulting company to help clients, including hospitals, better manage labs

CEO SUMMARY: Few independent pathology groups have developed robust laboratory consulting businesses. But adopting that strategy has brought important benefits to Delta Pathology Group, LLC, of Shreveport, Louisiana. Not only has providing lab consulting services to cash-strapped hospitals led to ongoing lab management contracts, but Delta's consulting arm, called Pathology Resource Network, is gaining a reputation for its expertise in helping hospitals improve their lab's performance.

WHAT'S A PATHOLOGY SUPERGROUP to do after it has achieved critical mass through consolidation of several smaller pathology groups in its primary service area? Form a laboratory consulting company, that's what!

This strategic decision was made back in 2003, by the executive committee of **Delta Pathology Group, LLC**, of Shreveport, Louisiana. In 2005, the pathology group founded **Pathology Resource Network, LLC**, (PRN). PRN started as a management company with 45 people that provided lab management and accounts payable services.

Since then, PRN has played an essential role in helping Delta Pathology and its 26 pathologists establish client relationships with physicians and hospital labs throughout Louisiana and surrounding states. In that regard, PRN provides an example to other pathology groups as to the importance of diversifying business services that can help attract new clinical clients and increase their loyalty.

The numbers tell the tale. "Today, PRN employs 112 full-time equivalent employees," stated Vivek K. Khare, M.D., FCAP, a Delta pathologist. "The Delta pathologists provide medical directorship for 50 hospital laboratories and provide testing services for 2,000 physicians in Louisiana. Delta Pathology has about 350 employees.

"Annual volume totals more than 2.25 million clinical lab tests, along with 215,000 surgical pathology accessions," he noted. "Our couriers travel 1.3 million miles across the state every year."

Major Growth Contributor

Pathology Resource Network has been a major contributor to growth at Delta Pathology. During strategic planning in 2003, Delta's executive committee performed a SWOT analysis (strength, weaknesses, opportunities, threats).

"Our SWOT analysis resulted in a 10-year plan to create a 'one stop shop' menu of services," recalled Khare. "We set out to expand our offerings in anatomic, clinical, molecular pathology, and genetic testing. To support this, we planned to expand our business and logistics infrastructure so we could offer lab management services, particularly to the smaller hospitals throughout Louisiana.

"During our analysis, we noted that national laboratories and out-of-state boutique laboratories were encroaching on our market," he continued. "As well, hospital systems were cutting costs and limiting capital spending for laboratory projects.

"We saw the opportunity to offer value in a new type of relationship with hospitals," added Khare. "We would offer a business solution to the problems some of our hospitals were facing with their laboratories. The solutions ranged from organizing traditional delivery of professional and technical services to offering solutions for laboratory consolidation and assistance, along with the due diligence required to assess whether or not to outsource the clinical laboratory.

"Further, we recognized that before we compete effectively against the national labs and these out-of-state boutique labs, we would need two things," he said. "First, Delta Pathology would have to offer a sophisticated menu of routine, reference, and esoteric laboratory services—supported by our specialist pathologists.

"Second, these clinical service strategies would require us to put in place sophisticated infrastructure specifically to excel in handling the pre-analytical and post-analytical phases of laboratory testing," noted Khare.

Demand For CLIA Assistance

It was at this stage that Delta Pathology's business strategy positioned it to take advantage of an emerging area of laboratory consulting. "As we put this plan into action, we saw a market need for CLIA oversight for rural hospitals in Louisiana," he said. "In 2005, we formed PRN and asked Marilyn Bullock, MT, ASCP, to assume the full-time role of CLIA consultant for PRN.

"The CLIA consulting and CLIA audits that she does are now our flagship offerings," stated Khare. "Hospitals in Louisiana rely on this work and we have out-of-state clients as well."

The fact that more rural hospitals in Louisiana need help with CLIA compliance in their laboratories mirrors a wider trend covered in this issue of THE DARK REPORT. *(See pages 3-10.)* More information about PRN's CLIA consulting services and experiences will be presented in the next issue of The DARK REPORT.

Hospitals Outsourcing Labs

On the subject of increased outsourcing of lab testing services by hospitals, Khare says that the change in technical component (TC) billing has definitely played an important role. "The trend toward more clinical lab outsourcing with hospital clients expanded after July 1, 2012," Khare said.

That is when the federal **Centers for Medicare & Medicaid Services** (CMS) eliminated the technical component exemption for certain lab tests. When the exemption was eliminated, labs could no longer bill separately for the TC work they did on some tests. Instead, the hospital billed for those tests and received the Medicare payment.

"Suddenly, pathology labs like ours were not getting the technical component income and had to bill the hospital for it," explained Khare. "Hospital administrators viewed that income as their own, thereby exacerbating the idea that the lab was a cost center and not generating any revenue.

"Most vulnerable to that thinking were administrators at hospitals that had no lab outreach or reference testing income," he said. "In these hospitals, not only are limited resources diverted to other departments, the laboratory now has to do more with even less.

"Delta and our new entity, **Omega Diagnostics Services**, now collectively own six clinical laboratories that have been acquired from hospitals that outsourced their inpatient and outpatient labs," added Khare. " This trend will continue as competing hospital departments divert unrestricted capital away from their

To Serve Local Physicians and Hospitals, Louisiana Pathologists Go 'Back to the Future'

"THERE WAS A TIME WHEN HOSPITALS or local pathologists operated all of the pathology services and lab testing services in a community," stated Vivek K. Khare, M.D., FCAP, a pathologist with Delta Pathology of Shreveport, Louisiana.

"But then, over the years, pathologists carved out the anatomic pathology and many hospitals sold their lab outreach services to one of the national lab companies," he continued. "When that happened, there were three different entities providing three different pathology services in most communities.

"At least here in Louisiana, the pendulum may be swinging back to a local emphasis for laboratory testing," offered Khare. "Seeking to increase efficiency, hospitals and labs are coalescing again into larger organizations."

It's a "Back to the Future" trend. "Like the 1970s, local pathology groups and local hospitals see value in doing both lab testing and lab consultations on site," he continued. "This provides the local labs with the best competitive advantage, particularly because boutique laboratories don't have those economies of scale due to their concentration on only one aspect of the lab industry.

"In those classic days of the 1970s and early 1980s, the traditional lab marketing strategy involved selling physician to physician," noted Khare. "At Delta Pathology, we are doing that now as we visit a doctor's office and offer to do their skin biopsies and provide clinical lab services too.

"Most everyone is interested in simplification," he emphasized. "In our region, physicians don't like the idea of sorting specimens and requisitions into different containers and having to call different labs to do different tests. This plays to our strength as a one-stop laboratory.

"It is why Delta Pathology offers not only anatomic, clinical, molecular, genetic, and reference testing, but also the IT infrastructure that physicians need, plus the management and consulting services for tertiary care hospitals and small rural facilities," observed Khare. "We also serve physicians' offices and hospital labs that need the efficiency we can provide. By consolidating the volume, we can improve efficiency.

"This is why we believe the trend is coming full circle where the one-stop-shop, offered largely by community laboratories, is in demand again," he concluded. "We are returning to a proven model of comprehensive laboratory testing services and a direct relationship between a local laboratory and local physicians."

laboratories, particularly in those health systems where the hospitals lack robust and profitable physician office outreach volumes."

PRN has found that the simple fact that hospital administrators identify their laboratory as a cost center can begin a downward spiral. "Here is what happens," noted Linda Price, PRN's Practice Manager. "The lab may not get the administrative support it needs to hire and retain adequate lab staff or buy supplies."

In addition to requests from hospitals for CLIA audits of their labs, Khare noted that, from PRN's earliest days, requests came from hospitals seeking consultations on laboratory consolidation, design, management, staffing, and outsourcing. "In situations where the hospital labs had little or no outreach revenue, the hospitals were eager to outsource their lab operations, if possible," he said.

"The national labs offer low-cost reference testing," observed Khare. "However, we can provide more comprehensive services, particularly medical directorship combined with lab management and CLIA consultation.

"In addition, our pathology group offers a clinical lab and molecular reference testing menu to complement traditional frozen section and professional/technical anatomic pathology services," he explained. "Finally, the ability for our laboratories to acquire hospital laboratories adds more value to the traditional clinical oversight roles we had played as medical directors.

"Local pathologists have an advantage over national labs," said Bruce Williams, M.D., FCAP, another Delta pathologist. "We just acquired a large lab that no longer had any outreach services and the physicians in that area wanted a local lab to do stat and anatomic tests locally.

"Keeping the lab testing local gave us a competitive advantage," emphasized Williams. "Local pathologists also have relationships with local physicians and other hospitals. We daily prove that a local pathologist can deliver efficiencies in addition to high quality pathology services. That gives us a competitive advantage over national lab companies."

➤Local Means Faster TAT

Khare agreed, noting that some hospitals in the region have TC contracts with national labs. "The national lab produces the slides and then the local pathologists read them out," he said. "But it often takes four or five days for the national lab to produce an H&E slide because it goes out of state after the specimen is grossed here. By contrast, with all the lab facilities we operate throughout the state, we can consistently produce slides in 12 hours from the time the specimen is procured."

THE DARK REPORT observes that the pathologists at Delta Pathology Group provide a useful example of how local pathologists can turn the tables on the national companies. However, to gain this competitive advantage requires a willingness to form a consolidated pathology practice, invest considerable capital to establish the needed infrastructure, and a willingness for the pathologists themselves to go out and develop new business. TDR

—Joseph Burns

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Delta Pathology and PRN Offer Range of Services

ONE MAJOR SOURCE of new business relationships for Pathology Resource Network (PRN) is its ability to consult with hospital and lab clients on how to comply with the Clinical Laboratory Improvement Amendments (CLIA).

"In addition, we provide a full menu of lab consulting services," noted Vivek K. Khare, M.D., a pathologist with Delta Pathology and PRN. "These range from laboratory design and lab management to business consulting on accounts payable, billing and coding. PRN provides logistics for courier and it also offers human resource consulting.

"PRN has considerable expertise in information technology," continued Khare. "Our laboratory information system has proprietary anatomic pathology features and can be connected to all of the following: EMRs, EHRs, web portals, health information exchanges, and interface services.

"Delta Pathology and PRN operate four histology labs, each with an associated IHC platform in strategic areas throughout the state and each one has a catchment area from which those specimens are procured and then processed," he commented. "Cytopathology and molecular testing are centralized to a core lab in Shreveport, which services the entire state.

"Regarding our clinical lab offerings, we have a consolidated full service lab in Shreveport and it covers the north and mid Louisiana" he stated. "In the greater New Orleans area, we recently acquired a clinical lab that will serve southeast Louisiana and the NOLA region."

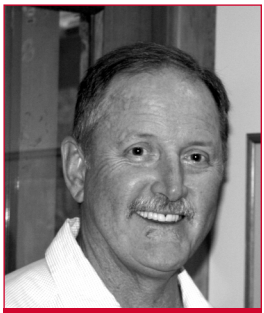
Obituary

Alan Lloyd, 62, Dies of Cancer, Formerly CIO of Sonic Health

THIS SUMMER, the global clinical laboratory industry lost a true innovator in medical laboratory management, operations, and informatics. On August 8, 2012, Dr. Alan Lloyd died peacefully at home from pancreatic cancer.

Lloyd was widely-respected for his unique approaches to laboratory operations, lab workflow, and use of informatics to support clinical assessment of laboratory test results.

Much of his work was done at **Sonic Healthcare, Ltd.**, of Sydney, Australia, where Lloyd served for more than two decades. As Chief Information Officer (CIO), he was an early member of the executive team that grew the company from its roots as **Sonic Technology Australia Limited** into the multi-billion-dollar global enterprise that it is today.



Dr. Alan Lloyd
1950-2012

Born in South Africa, Lloyd earned his MB.ChB at **Godfrey Huggins Medical School**, **University College of Rhodesia** in 1974. He next earned an M.MED (Chemical Pathology) from the **University of Cape Town** in 1982.

Practical Problem Solver

Lloyd's innovative nature did not take long to surface. In 1984, he was one of the pathologists who founded **City Park Private Laboratory**. He described this lab facility as "highly automated and with a sophisticated laboratory computer." Lloyd played a key role in developing what he described as "discriminant analysis programmes for the following test panels: lipid studies, glucose tolerance tests, thyroid functions, liver functions, and full blood counts." In 1986, his work was demonstrated using a live computer at the South African Pathology Congress.

In I987, Lloyd emigrated to Australia and began working at a hospital laboratory. Within a few years, he was back in private practice at **Macquarie Pathology**. He then joined **Douglass Hanly Moir** (DHM) as a chemical pathologist.

Almost immediately, DHM became part of Sonic Healthcare and the company began to grow by acquiring other pathology laboratories. Lloyd's keen interest in software system design and laboratory automation was quickly recognized and he was rewarded with the promotion to the position of Chief Information Officer for Sonic Healthcare, where he remained until he retired in 2010 after a diagnosis of pancreatic cancer.

Lloyd had a practical approach to problem solving. His most fertile work was in two areas: streamlining laboratory workflow and using information technology (IT) to unlock more useful clinical knowledge from laboratory test data. He was also ahead of his time in using software and the laboratory information system (LIS) to support workflow in pre-analytical, analytical, and post-analytical phases of lab testing.

It was during the 1990s, when the first laboratories in the United States were spending millions of dollars to install the

first generation of total laboratory automation (TLA). At the same time, Lloyd was moving toward the same automation goals in Sonic's highest-volume lab facilities, but spending only tens of thousands of dollars.

THE DARK REPORT viewed Lloyd's innovations during site visits to Sonic Healthcare's labs in Melbourne, Sydney, and Brisbane. Lloyd was using inexpensive, off-the-shelf industrial conveyor belts, modified with six to eight "channels," to move specimens from reception to processing.

Industrial Conveyor Belts

As the accessioner logged in the specimens, he/she would lay the specimen on its side in the channel which would transport it directly to the correct test station—whether hematology, automated chemistry, or other. The conveyor belt would then move that specimen directly to the proper location.

When asked why his automated solution didn't use individual transport pucks and hold specimens upright, as was typical of the first generation TLA sold by the *in vitro* diagnostics (IVD) manufacturers, Lloyd had a common sense answer: "Specimens travel on their sides in courier cars. So why not travel on their sides within the lab until they get to the pre-analytical staff for centerfuging, aliquotting, and the like?"

Meanwhile, under this conveyor belt was a second off-the-shelf conveyor belt. When the accessioner completed data entry, he/she would put the paper requisition on this conveyor belt. That requisition was transported to the end of the line where another staff member gathered it and immediately scanned the requisition, so it could be viewed digitally within the LIS.

It was a similar story with how Lloyd used information technology. He was equally ahead of his time in deriving the "values" of clinical lab and pathology informatics and putting them in practice in real life patient care. Within Sonic Healthcare, he developed a dynamic expert pattern recognition software called Morpheus.

Morpheus automatically analyzes complex current and previous patient test results, demographics, clinical attributes, and other "discrete" data such as medication use. The agile, powerful, and yet simple design of the software meant that it was easily adopted by Sonic's pathologists to analyze complex patient lab and clinical information. Lloyd, as a trained pathologist, wanted laboratory informatics to be a tool that helps clinicians solve real life issues.

Lloyd's approach to pattern recognition illustrates why his ideas were so productive. In pattern recognition, investigators typically take patient data and compare it to pre-established known "patterns" derived from scientific knowledge. Lloyd turned this approach upside down.

He did the "reverse" analysis. Lloyd took large volumes of population data and ran it through the Morpheus pattern recognition engine, asking the computer to find common patterns within the population. By doing so, he mitigated the limitations and reliance on personal scientific knowledge by supplementing it with "artificial intelligence" of the computing power and increased real life applications.

Finding Patterns With IT

Lloyd took such analysis one step further by expanding the data source to include healthcare financial claims. He could then identify patterns of costly clinical attributes, along with specific clinical variables associated with significant healthcare cost. These analyses have identified opportunities for population management targets and provided predictive modeling for health insurance benefit design.

In the approaching world of accountable and coordinated healthcare, Lloyd's legacy is the expertise, approaches, and informatics tools that pathologists can use to assume a leadership role within these emerging healthcare delivery systems. In that regard, Lloyd's lifetime of innovations in automation and informatics positions pathology to deliver that value. TDR

Med Tech Finds "Grace" Aboard Lab of Mercy Ship

Hospital ship *Africa Mercy* has high-tech clinical laboratory staffed totally by volunteers

CEO SUMMARY: ***One intrepid medical technologist has spent almost two decades in volunteer service working in the clinical laboratories of hospital ships operated by Mercy Ships International. As the world's largest hospital ship, the* Africa Mercy *contains six operating rooms, a 78-bed ICU and patient ward, along with a clinical lab that is equipped with state-of-the-art instruments and lab systems. Lab professionals have an opportunity to volunteer to serve aboard the* Africa Mercy*.***

MEDICAL LABORATORY PROFESSIONALS looking to volunteer their services may be interested in serving aboard the *Africa Mercy*, the world's largest hospital ship.

Colleen S. Conley BS, MT(ASCP), CLS is the Medical Laboratory Director for **Mercy Ships International** and did her first volunteer service with the program back in 1995. She is among the many professional healthcare volunteers working onboard the *Africa Mercy*, which brings help and hope to Africa's poorest residents.

Mercy Ships International is a Texas-based, faith-based, non-denominational charity with satellite offices around the world. It operates the *Africa Mercy*, a ship that features six state-of-the-art operating rooms. It also has an intensive care unit and ward with beds for up to 78 patients, a clinic, and a 438-berth capacity.

"The laboratory aboard the Africa Mercy is comparable to that of a lab in a rural hospital," noted Conley. "It is equipped with state-of-the art instruments needed to perform a full-range of diagnostic tests and procedures.

"The lab's test capabilities include hematology, biochemistry, immunology, microbiology, urinalysis, serology, and tropical medicine," she added. "It also has a blood bank and can handle cytology and histology specimens.

"We aren't equipped to do DNA testing, but we can do stains for histology assessment," noted Conley. "These specimens are analyzed by remote volunteer pathologists, who are sent the dried stains by mail. Results are returned to us electronically."

Digital Images For Cytology

For cytology specimens, the lab uses a **Nikon** Coolscope Digital Microscope to capture digital images of tumor biopsies and transmit them to an Internet storage site. Remote pathologists log on to the lab's website and download images for analysis, said Conley, noting that this technology allows the ship's doctors to get results back quickly, even in West Africa.

"There are similarities in running a lab aboard the ship, but also challenges not ordinarily encountered on land," she stated. "Both space and geographical constraints

present logistical issues. For example, lack of room for large instruments and the remote locations visited by our ship limit our laboratory equipment choices.

"This lab is very technologically advanced and automated," noted Conley. "But when considering instrumentation and procedures for use in West Africa, we have to look at what can be sustained. For instance, it can take weeks to find an engineer to fix equipment that breaks down."

Africa Mercy's lab has three full-time lab technicians, plus temporary volunteers, all of whom come from nations around the world. "While diversity is very exciting and rewarding, it can make it hard to staff a lab and get everyone to gel," Conley continued. "Additionally, the continuous changeover in personnel—combined with the ship's movement from port to port—means that the environment is constantly changing, and we're always in a training mode."

Additionally, volunteers often need to brush up on lab skills like phlebotomy, which they may not routinely use on their regular jobs. Conley explained that the operating room depends on the ship's "walking blood bank" of volunteers for all needed blood products, so lab technicians should be able to screen donors and draw blood.

Advanced Lab Technologies

"The heart of the matter is that working on the *Africa Mercy* is incredibly rewarding," declared Conley. "It is rare to find an opportunity in these regions where you can use advanced clinical lab technologies and skills to help," adding that "the *Africa Mercy* provides an advanced hospital setting in a third-world environment, where there is no access to high-tech medical services."

Laboratory and other medical professionals interested in volunteering on the *Africa Mercy* can explore short- and long-term volunteer opportunities posted on Mercy Ships International's website at: *www.mercyships.org*. While laboratory staff positions require a two-year commitment, she noted that there are frequent openings for temporary lab volunteers for tours lasting two to three months. TDR

—By Patricia Kirk

Contact Colleen Conley via email at: colleen.conley@mercyships.org.

Africa Mercy's Volunteers Must Provide Resources

IT WAS A THREE-MONTH TOUR in the ship's galley of the *Africa Mercy* which was Colleen Conley's first volunteer service back in 1995.

"I fell I love with the charity and organization, so the next year I quit my job and volunteered as a lab tech," she said.

Being a volunteer on the *Africa Mercy* requires sacrifice. Volunteers must pay their own way, and there are no stipends to help with expenses. Room and board fees range between $167 and $525 per month, depending on the volunteer's country of origin and length of tour.

"Additionally, volunteers are responsible for their own associated travel costs, immunizations, passports, and other personal expenses, including health insurance," stated Conley. "Volunteers must also purchase emergency evacuation and repatriation insurance."

Conley receives financial support from family, friends, and churches, whose members believe in the work of this charity, but cannot volunteer. Transitioning from a clinical to administrative role, she is now based in Virginia and travels when needed aboard ship.

Conley admitted that her financial future is a big question mark after almost two decades of volunteer service, as there's no nest egg for retirement. But she has no regrets and wouldn't trade her life and experiences on the *Africa Queen* for any amount of money or security. "I guess I just have to wait and see," she observed, "and have faith that I will be OK."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

OURLab and its parent company, **Prost Data, Inc.**, of Nashville, Tennessee, entered into an agreement to be sold to **Opko Health Inc.**, of Miami, Florida. The purchase price of $40 million will be paid as $9.4 million in cash and $30.6 million in stock. Publicly-traded Opko has both pharmaceutical and diagnostic product lines. Jonathan Oppenheimer, M.D., founder of **Oppenheimer Uro logic Reference Laboratory** (OURLab) will become Chief Executive Officer of OPKO's diagnostics division.

MORE ON: *Opko*

Opko says that it will use OURLab to help it launch and sell its 4Kscore test, which it describes as a "novel panel of kallikrein biomarkers and associated algorithms for the detection of prostate cancer." Opko is launching this test in Europe. Opko says that its proprietary test, "has been demonstrated in more than 10,000 patients to predict the probability of positive biopsies in men suspected of having prostate cancer... and use of the 4Kscore may reduce the number of unnecessary prostate biopsies by 50% or more."

TRANSITIONS

- **Rosetta Genomics** of Philadelphia, Pennsylvania, announced that E. Robert Wassman, M.D., will serve in the new position of Chief Medical Officer and Chief Scientific Officer. Wassman, has held executive positions with **Generation Health**, **Genzyme Genetics**, **Alfigen**, **Good Start Genetics**, **Genetrix**, and **Specialty Laboratories**.

- **StrataDx** of Lexington, Massachusetts, hired Jim Agnello to be Chief Financial Officer. Agnello has held executive positions with such lab companies as **Clarient**, **Genzyme Genetics/Impath**, and **SmithKline Beecham Clinical Laboratories**. StrataDX also hired Greg Richard as its new Executive Vice President of Sales and Marketing. Richard formerly held executive positions at **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**.

- **Pacific Diagnostic Laboratories** (PDL) of Santa Barbara, California, has appointed Sonny Varadan as its Chief Information Officer. PDL is a client laboratory of the **Nichols Management Group**. Varadan was most recently the Vice President and CIO of **Pathology Associates Medical Laboratories**, and was formerly the Interim CIO for **Providence Health Care** of Spokane, Washington.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 19, 2012.