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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Preparing for the Medicare-Medicaid Buzz Saw

MEDICAID PROGRAMS IN TWO STATES ARE CURRENTLY TARGETING laboratory testing services as a source of cost savings. It's not coincidental that the states involved are Florida and California. During the past 15 years, both states have stayed at the cutting edge of managed healthcare. Many "innovations" (read: a way to pay providers less for the same service) have started in these two states, then been copied by payers in other states.

It is this history of being first to introduce experimental new approaches to controlling utilization and reducing reimbursement that draws my attention. Once again, Medicare officials in both Florida and California are ready to implement radical changes in long-standing procedures for authorizing providers and establishing reimbursement levels. In both cases, the primary target is laboratory testing services.

These are not auspicious developments for the laboratory testing industry. It has just finished a tough fight to avoid the re-imposition of a 20% co-pay for lab testing under the Medicare Part B schedule. Now, on both coasts, two of the nation's largest states—caught in difficult budget squeezes—have drawn a bead on laboratory testing services as the potential source for cost reductions. I see this as a portent of what can be expected to spread to the Medicaid programs in other states.

Because of the significant presence maintained by government health programs such as Medicare and Medicaid in many regions, radical and arbitrary attempts by healthcare bureaucrats to squeeze out more concessions from clinical laboratories will grow in number. I believe that most laboratory directors and pathologists are not psychologically ready to deal with this new development. I predict we will see a noticeable shift in longstanding Medicare and Medicaid policies.

Going forward, everyone agrees that government-funded health plans will lack the financial resources required to support the increased demand for health services. No one questions the impact of current demographic trends. If you match this consensus against the "surprise" introduction of new lab services contracting arrangements by Medicaid officials in Florida and California, one obvious conclusion is that Medicare and Medicaid programs are becoming a financial buzz saw, ready to cut into the heartwood of the lab industry's finances. TDR

Calif. Medicaid Prepares To Issue Lab Contracts

Agency will use contracts to restrict labs which can legally bill for Medicaid testing

CEO SUMMARY: California Medi-Cal officials may be creating more problems than they solve with their latest scheme to have independent laboratories sign contracts with their Medicaid program—while excluding hospital laboratory outreach programs and labs operated from physicians' clinics and offices. Nominally, the goal is to reduce fraudulent lab test claims submitted to the California Medicaid program.

CALIFORNIA'S LABORATORIES SEEM to be in the crosshairs of its state Medicaid program.

"First came a cut in reimbursement last fall," stated Richard Nicholson, President and CEO of **Westcliff Medical Laboratories** in Newport Beach, California. "Medi-Cal, our state's Medicaid program, instituted a fee schedule for laboratory testing that was 80% of Medicare fees or less for individual laboratory tests.

"Then, on April 5, 2004, the **California Department of Health Services** (DHS) mailed a cover letter and a Request for Application (RFA) to 500 independent laboratories in the state," continued Nicholson. "Medi-Cal intends to sign contracts with a specific number of laboratories that best meet its criteria. If a laboratory doesn't have a Medi-Cal contract, it will not be reimbursed by Medi-Cal for Medicaid testing."

Medicaid laboratory testing initiatives in California represent an unsettling counterpoint to efforts by Florida's Medicaid agency to award a single laboratory the right to perform all Medicaid lab testing in Florida for three years. *(See TDR, April 5, 2004 and April 26, 2004.)*

Current efforts to control laboratory testing costs by Medicaid agencies in California and Florida should be closely tracked by laboratory administrators and pathologists across the country. As Medicare agencies in other states face a growing funding deficit, it can be expected that they will imple-

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

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ment similar initiatives to constrain and control the cost of laboratory testing in their state.

"In general, the laboratory industry in California is opposed to this Medi-Cal contracting scheme," stated Michael J. Arnold, Legislative Advocate for the **California Clinical Laboratory Association** (CCLA), based in Sacramento, California. "Over time, it will create many more problems than any it attempts to solve.

Excludes Many Labs

"First, Medi-Cal is asking 500 independent laboratory companies to apply for a contract. This ignores hospital laboratories with laboratory outreach programs, physician office labs (POLs), and labs in clinics and physician group practices, all of which will continue to provide testing to Medicare beneficiaries," explained Arnold.

"Second, the application is a complex, onerous process, full of ambiguities," he continued. "Among other things, Medi-Cal has sent this RFA out to labs holding a CLIA license for moderate or complex testing. Each laboratory company must submit a separate and complete application for every CLIA-licensed site it operates.

"Third, Medi-Cal's RFA says it will award contracts only to the 75% of the laboratories which score highest on their point system," added Arnold. "Medi-Cal officials have since stated that this will be changed. Last week they suspended the RFA process to revamp aspects of the RFA. They will also allow any laboratory which achieves a certain score on the RFA scoring system to be a Medi-Cal provider.

"Fourth, Medi-Cal has frequently declared that fraudulent laboratory testing claims are a significant problem," he said. "Medi-Cal hopes that these laboratory contracts will cut down such fraud. However, the source of much fraudulent lab billing is not an independent laboratory company with proper licenses, it is from physicians and laboratories operated in physicians' offices. Medi-Cal's laboratory RFA leaves this source of fraud completely unaddressed."

After mailing the RFAs on April 5, Medi-Cal conducted public meetings in Southern and Northern California. It had originally set May 17 as the application due date. "That was extended to June 22, 2004, before the RFA process was suspended." noted Nicholson. "Medi-Cal says it will announce the names of laboratories granted a contract by October 1, 2004."

Should Medi-Cal implement laboratory contracts as it plans, THE DARK REPORT can identify a number of serious ramifications to California's competitive laboratory testing marketplace. Moreover, California has a reputation as a bellwether state in healthcare. Any initial successes that result from Medi-Cal's lab contracting program will motivate Medicaid programs in other states to copy Medi-Cal's laboratory contracting program. So the long-term impact may reach beyond the borders of California.

Freezing Lab Competition

First, Medi-Cal has already frozen the competitive status quo. The newly-announced plan to contract with a limited number of laboratories will intensify that competitive freeze. "About two years ago, Medi-Cal instituted a moratorium on issuing Medicaid licenses to new laboratories," stated Nicholson.

"This moratorium denies any new laboratory access to Medicare patients. With Medi-Cal now preparing to sign contracts with a finite number of laboratories, new laboratories will find it more difficult to enter the market, to expand into other regions of the state, and to include Medicaid patients in their test mix," explained Nicholson.

Medi-Cal's Lab Strategy a Replay Following Earlier Budget Crunches

FOR SOME PEOPLE WITH LONG MEMORIES, Medi-Cal's attempts at laboratory contracts is déjà vu. A variant of this scheme was tried before, during an earlier budget crises in 1992.

"Desperate times create desperate actions," noted Michael J. Arnold, Legislative Advocate for the California Clinical Laboratory Association (CCLA) in Sacramento, California. "When California undergoes a serious budget crisis, the Medi-Cal program often takes radical actions to control costs.

"The last time Medi-Cal tried to put the state's clinical laboratories under contract was 1992," he recalled. "There was a budget crisis that year and lab contracting was one strategy to slash Medicaid costs. CCLA opposed that initiative and succeeded in having laboratory contracting proposals withdrawn at that time.

"However, laboratory managers and pathologists today should not be surprised at Medi-Cal's contracting strategy. Medi-Cal has a long history of using contracts to control prices and access to health services. Medi-Cal originally put hospitals onto contracts during an even earlier budget crisis," explained Arnold. "That was in 1982.

"Prior to the first Medi-Cal hospital contracts in that year, patients were free to choose from any hospital in the state," he continued. "In 1982, Medi-Cal negotiated favorable pricing and terms with selected hospitals in different regions of the state. After it boldly limited patient choice of hospitals that year, private health insurers jumped on the same bandwagon and began to contract with hospitals and physicians to create provider networks that limited a patient's choice."

"Medi-Cal's contracts with laboratories will also change the way it handles allegations of Medicaid fraud and abuse," explained Arnold. "Under these new contracts, the burden of proof shifts. Currently, Medicaid must prove allegations of fraud before it can pull the Medicaid license of an offending laboratory.

"Once these contracts are executed between a laboratory and Medi-Cal, it will have the legal right to pull the lab's Medicaid license if any clause of the contract is violated," he said. "From the perspective of regulators, they now have a more efficient tool to punish suspected violators."

Second, Medi-Cal's lab contracting scheme creates an uneven playing field. It appears that hospital laboratories with outreach programs will not be required to apply for a Medicaid contract, so long as they use their hospital's provider number when billing for lab tests. Competitively speaking, that gives them a free hand over independent lab companies to build their market share of Medicaid testing.

From the perspective of Medi-Cal bureaucrats, excluding hospital labs from the contract program is reasonable. One goal of Medi-Cal's lab contracting program is to attack sources of fraudulent lab testing claims. Hospitals do not fit Medi-Cal's profile of providers likely to submit fraudulent lab test claims.

Third, it shifts the burden of proof in cases of Medicaid fraud and abuse. Prior to the implementation of laboratory contracts, it was up to federal and state investigators to gather the evidence necessary to successfully prosecute a case of suspected fraud. Language in these contracts will require laboratories, and their managers, to waive constitutional rights and be bound to

regulatory procedures that govern violations of state and federal Medicaid statutes and regulations.

Fourth, these contracts will distort the existing market supply of laboratory tests for Medicaid patients. It replaces the existing policy, generally one of "any willing provider," with a scheme that puts government officials in the position of deciding which laboratory providers will be given favored status.

"CCLA has opposed this concept from its inception," declared Arnold. "CCLA continues to be opposed. However, it also understands how California's current budget crisis stimulates these types of proposals."

Effectively, this allows Medi-Cal officials to decide which laboratories will be winners and losers when it comes to Medicare laboratory testing services. This consequence can already be seen in the first round of this new lab contracting program. Only independent labs holding a CLIA license for moderate or complex testing must apply for a contract. Hospital laboratory outreach programs and physicians' office laboratories are exempted.

Lab Industry Response

How independent laboratories in California respond to this Medi-Cal contracting initiative has yet to be seen. "Initially, independent laboratories viewed these contracts as a better option than competitive bidding," observed Nicholson. "Now that labs have seen the first details of this contracting program, there is sure to be determined opposition on several key points. Undoubtedly a number of labs have their lawyers reviewing Medi-Cal's RFA and that may lead to individual labs filing legal challenges to this RFA process. But nothing yet has happened on that front."

"CCLA opposed this concept from its inception," declared Arnold. "CCLA continues to be opposed. However, it also understands how California's current budget crisis stimulates these types of proposals. On behalf of the state's laboratories, CCLA is already working to clarify ambiguities and eliminate the onerous parts of this Medicaid contracting program."

The implications of Medi-Cal's new laboratory testing initiative should be viewed in conjunction with lab testing reforms underway within two other government health programs. One is Florida Medicaid's effort to bid all Medicaid testing statewide to one laboratory under a three-year contract. The other is in British Columbia, where health authorities are attempting to reduce laboratory fees by 20% while instituting competitive bidding for laboratory testing services in the province. *(See TDR, April 26, 2004.)*

Radical Changes Predicted

Collectively, these three examples illustrate how rapidly the status quo between government health programs and laboratories in both the United States and Canada will undergo radical shifts. Financial desperation will drive much of this "reform" because government health authorities don't have adequate money to fund services at existing levels.

Laboratory administrators and pathologists should take these developments as an early warning. In coming years, any lab which relies on revenues from Medicare and Medicaid testing is likely to find itself getting paid less or being excluded from such testing. TDR

Contact Richard Nicholson at 949-646-0216 and Michael Arnold at 916-446-2646.

Beckman Loses Auction To Buy Lab-InterLink

Cardinal Health almost "stole" Lab-Interlink at a bargain price—until a court-ordered auction

CEO SUMMARY: ***For laboratories with automation equipment from Lab-InterLink, the sale of the troubled company to Cardinal Health is good news. At the same time, interesting questions are triggered by this development. What plans does Cardinal Health have for the laboratory testing marketplace? Was Beckman Coulter bidding for Lab-InterLink as a way to acquire the technology and keep it off the market?***

THERE'S NOTHING like an auction among interested buyers to generate the highest price for the seller.

In this case, an auction of the assets of **Lab-Interlink, Inc.** directed by a federal bankruptcy court in Omaha, Nebraska converted a single purchase offer of $550,000 into a sales price of $3.25 million. Lab-InterLink makes laboratory automation equipment and software. It ran out of working cash last November and that's when things began taking unusual turns. Like an O. Henry short story, the Lab-Interlink tale has several fascinating twists and a surprise ending, a least for the current chapter.

Cash Ran Out In November

That chapter began last November. Attempts during 2003 to raise additional capital were unsuccessful. When the last of Lab-InterLink's money ran out that month, it was forced to lay off most of its employees and continue with a skeleton staff. *(See TDR, February 2, 2004.)*

Lab-InterLink's founder and CEO, Rodney S. Markin M.D., Ph.D., continued searching for investors or buyers. The interested buyer turned out to be **Cardinal Health, Inc.** of Dublin, Ohio. Cardinal Health signed a purchase agreement with Lab-InterLink and agreed to pay $550,000 for the troubled company, with a closing date set for May 20, 2004. This purchase was to take place as part of a Chapter 11 bankruptcy action by Lab-InterLink.

The bankruptcy was necessary because Lab-InterLink had assets of approximately $2.8 million, but liabilities totaling almost $15 million. A Chapter 11 bankruptcy filing would allow Lab-Interlink to wipe out these debts and let Cardinal Health take clean title to the company.

Early in April, Lab-Interlink went to federal court in Omaha, Nebraska and filed its Chapter 11 bankruptcy action. When news of the bankruptcy became public, several interested parties showed up to object.

One group represented employees who filed claims for unpaid salaries and expenses totaling $375,000. An-

other objector was the **University of Nebraska** (UN), which holds the patents Markin developed in his position as Professor of Pathology at the UN Medical School. It was concerned over the status of the patents.

Auction Set For May 5

With Lab-InterLink now in bankruptcy court, Cardinal Health and Markin expected the court to approve the sale to Cardinal as part of the company's restructuring plan. Here's the next twist in the story. The bankruptcy judge ruled on April 22 that a public auction would be held on May 5. If no other bidders appeared on that date, the company would be sold to Cardinal Health for $550,000.

In the days following the bankruptcy filing, two other buyers had expressed interest. But on auction day, only one other buyer appeared. That was **Beckman Coulter Corporation** from Fullerton, California.

Over the course of 12 rounds of bidding, the final purchase price climbed from $550,000 to $3.25 million!

In a conclusion worthy of O. Henry, the auction took some unexpected twists and ended up with a surprise ending. Over the course of 12 rounds of bidding, the final purchase price climbed from $550,000 to $3.25 million! And the winning bidder? It was Cardinal Health. Beckman Coulter refused to raise its last bid of $3.2 million and went home empty-handed.

In another twist to the story, founder Markin and his wife, Annette, another Lab-InterLink creditor, pledged to the court stating that they would set aside $250,000 of the money they receive from the sale to Cardinal Health to be applied toward the salaries of former employees. The employees' salary claims are unsecured. The Markins are the first of four secured creditors and say they are owed $2.5 million from Lab-InterLink.

When Lab-InterLink is sold to Cardinal Health, it will end that chapter of its story and begin a new chapter. Cardinal Health plans to invest significant capital in Lab-InterLink. It intends to take over the company's offices, rehire employees, and operate the business from Omaha.

Pharmacy Automation

With its purchase of Lab-InterLink, Cardinal Health will assume a larger presence in the diagnostic testing marketplace. The company employs 50,000 people and has annual revenues of $60 billion. Its main source of revenue is pharmaceuticals distribution. But it does have a division that sells automation and information services. Its Pyxis MedStation® is a big-selling automated pharmacy system. Lab-Interlink, with both its hardware and software solutions, is probably seen as complementary with Cardinal Health's pharmacy automation.

The interesting player in this story is Beckman Coulter. **Coulter Corporation**, before its acquisition by Beckman in 1997, had invested in Lab-InterLink. Beckman offers its own line of laboratory automation equipment. After the auction for Lab-Interlink, its attorney, Richard Myers, stated that Lab-InterLink considers Beckman Coulter to be a competitor that would probably have pulled Lab-InterLink's technology off the market had it been the winning bidder.

It will be welcome news to Lab-Interlink's lab customers that its buyer is a big and financially-healthy corporation. Many customers have struggled to keep their Lab-InterLink products operational during the past six months. TDR

Molecular Diagnostic Trends

ASCP's "Molecular Pathology" Certification Now Available

Medical Technologists working in this field can qualify for the designation MP(ASCP)

RECOGNIZING the growing importance of molecular pathology, the **American Society of Clinical Pathology** (ASCP) established a new certification program in this diagnostic specialty.

Offered since June 2003, 18 people have passed the examination and can use the designation "MP(ASCP)." Prerequisites for the MP designation are a baccalaureate degree and on-the-job training in molecular pathology.

This sets the MP designation apart from other MT certifications, such as blood bank or chemistry. These generally require a prescribed route of education, a post-baccalaureate degree coupled with three years of full-time acceptable clinical laboratory experience in the exam specialty (done under the supervision of a pathologist), and an examination.

Molecular Pathology

ASCP's MP certification was designed to reflect an essential fact. Molecular pathology skills are in high demand. Thus, medical technologists trained in this work are usually not cross-trained and rotated into other sections of the laboratory. Their duties tend to be exclusively focused on molecular testing responsibilities.

Among other things, a candidate for the MP certification must demonstrate that he/she is capable of performing a full range of molecular laboratory procedures, including interpretation of standard, complex, and specialized tests. The candidate must also demonstrate an understanding of all the associated quality controls, troubleshooting techniques, validation procedures, and preventative maintenance of instruments used in molecular procedures.

Included in the examination are questions on solving problems, analytical decision-making, effective methods for communicating test results and explaining the methodologies to other health professionals and consumers. Other requirements address teaching and training responsibilities, along with supervision and management issues.

Candidates can take the MP examination anytime during the year. The exam is offered in a computer-based format at **NCS Pearson Professional Centers** located throughout the United States.

The ASCP Molecular Pathology Examination Committee is chaired by Frederick Nolte, Ph.D., Professor of Pathology and Laboratory Medicine at **Emory University School of Medicine** in Atlanta. He is also the university's Director of Clinical Microbiology and Molecular Diagnostic Labs. TDR

For detailed information visit the ASCP Board of Registry Website at www.ascp.org/bor*; or call 312-738-1336, ext 1430; or fax to 312-738-5808; or email to bor@ascp.org*

—By June Smart, Ph.D.

CEO SUMMARY: Here's an exclusive peek into a three-year battle between medical technologists wanting to do the right thing and a laboratory manager—backed by hospital administration—who aggressively stifled well-justified dissent. It is an inside look at one of the most grievous failures of a hospital-based laboratory in several decades. By knowingly reporting unreliable test results, the laboratory at Maryland General Hospital put patients at risk. But that's just one aspect of this sordid tale.

PLENTY OF "NOT-TO-DO" LESSONS FOR LAB MANAGERS

Baltimore Hosp. Lab Problems Put Spotlight On CAP Inspections

PUBLIC SCRUTINY of the laboratory at **Maryland General Hospital** in Baltimore continues to trigger remarkable disclosures and embarrass any number of healthcare organizations.

Not the least of these is the **College of American Pathology** (CAP). In April 2003, its inspectors visited the laboratory at Maryland General Hospital (MGH). In the report based upon this inspection, the MGH laboratory was given CAP's highest performance rating: "accredited with distinction." It is now known that, for at least several years, the problem-plagued MGH laboratory was reporting questionable test results to physicians and patients.

But CAP is not the only embarrassed party. Several inspections by the Maryland **Department of Health** (DOH) during that same year failed to identify operational failings at the MGH laboratory. Even as his own agency's inspections came under scrutiny, Nelson J. Sabatini, Maryland's State Health Secretary, was particularly critical of the CAP laboratory inspection process.

Failure Of "The System"

This sensitivity is understandable. It took a medical technologist-turned-whistleblower to blow the lid off the failings at MGH's laboratory. Kristin Turner's letters to the Maryland DOH in December 2003 triggered a series of laboratory inspections over the next 60 days. It wasn't until March 2004 that government agencies finally told the public about the true scope and scale of problems at the MGH laboratory.

The hospital was forced to make a public announcement that HIV and HCV testing done on more than 2,000 patients over an 18-month period had produced unreliable results. It launched a program to publicize this fact, locate the individuals, and get them in for retesting. As a result of this lab scandal, resignations were accepted from the hospital's CEO, from Laboratory Director James Stewart, and from Medical Director Philip Whalen, M.D. *(See TDRs, April 5, 2004 and April 26, 2004.)*

The problems at Maryland General Hospital's laboratory story are highly significant. This may be the worst failure of laboratory operations in a hospital in the past decade, possibly longer. It also demonstrates how public intolerance is increasing for institutional failures within healthcare that affect patient outcomes. This change in public attitude raises the stakes for any laboratory that delivers laboratory testing services of unacceptable quality.

THE DARK REPORT is closely tracking ongoing public disclosures about the problems and failings at the Maryland General Hospital Laboratory. It is in possession of a range of internal documents, dating back as far as 2002. It also has copies of recent inspections of the laboratory by the Maryland DOH.

With this information, it is possible to do a preliminary forensic management analysis of the MGH laboratory. The result is useful insights, conclusions, and recommendations for clients and readers of THE DARK REPORT.

Major Failures In The Lab

The basic list of operational breakdowns runs a wide gamut: 1) failure of laboratory management, at the level of both the laboratory administrator and the laboratory medical director; 2) failure of both government and non-government laboratory inspectors to uncover ongoing operational problems with the potential to negatively affect patient care; 3) failure of middle managers and technical staff in the laboratory to successfully attract the attention of lab management, hospital administration, and various inspecting agencies to the lab's operational deficiencies and problems; 4) failure of hospital administration to respond to the warnings provided by concerned laboratory staff; 5) failure of internal laboratory systems to identify, respond, and correct fundamental flaws with diagnostic instruments, reagents, and opera-

Adaltis U.S. Sidesteps Its Growing Problems

CENTRAL TO THE PROBLEMS at the laboratory of Maryland General Hospital (MGH) is a laboratory instrument called the LABOTECH, manufactured by **Adaltis Italia S.p.A.**, based in Rome, Italy.

LABOTECH instruments were marketed in the United States by **Adaltis US, Inc.**, based in Allentown, Pennsylvania. When the laboratory problems at Maryland General Hospital became public in March, failures of its LABOTECH instrument received prominent mention in press coverage.

Moreover, Adaltis US found itself sued by Kristin Turner, the MGH med tech who claims she was infected with HIV and HCV as a result of malfunctions and poor design of the Adaltis LABOTECH. Adaltis US moved swiftly. By April 13, 2004, it had sold itself to **Trinity Biotech plc** for a price of $3.5 million.

Trinity is based in Dublin, Ireland. It sells 500 diagnostic products through distributors in 80 countries. It has moved the Adaltis US operations to a distributor in Montreal, Quebec, Canada and now calls that operation Adaltis, Inc.

THE DARK REPORT spoke to former employees of Adaltis US, Inc. It learned that Adaltis US, Inc. marketed the LABOTECH in conjunction with a test menu involving approximately 100 different tests. These tests represented reagents provided by almost 20 different companies. At least one ex-employee says that Adaltis US knew that some of these tests could not produce accurate results when used with the LABOTECH. But this information was not disclosed to potential customers at the time of sale.

Further, these employees note that Adaltis US did not maintain a laboratory in the United States. Thus, it neither validated or calibrated the tests it sold with the LABOTECH, nor could it perform studies on different batches of reagents. Assuming these observations are accurate, it helps to explain why the MGH laboratory had virtually non-stop problems with the lab test results generated by its LABOTECH instrument.

tional protocols; 6) allegations of wrongful coding and billing for certain laboratory tests; and, 7) failure of the hospital's organization culture to support people attempting to "do the right thing."

To give context to these failures, a brief history of events at Maryland General Hospital's lab will be helpful. The following outline builds on coverage provided by THE DARK REPORT in previous issues.

Rundown Of The Facts

Maryland General Hospital is a 245-bed community hospital which serves a poorer neighborhood of Baltimore. In the past three years, it became a part of the **University of Maryland Health System** (UMHS).

Internal lab memos dating back to 2001 indicate problems with inadequate laboratory staffing, due to budget constraints. This was particularly true in the chemistry department. During this period, a new laboratory administrator, James Stewart, was hired.

The laboratory's technical staff could see a range of operational problems. Individuals were quite vocal about bringing these issues to the attention of both laboratory management and hospital administration. Memos and letters document repeated meetings on these topics and reveal that, for various reasons, senior laboratory management was able to refute such claims and satisfy hospital administration that no serious problems existed in the laboratory.

Problems Of Short-Staffing

That belies the facts presented by the vocal component of the laboratory staff. Some examples from these memos and letters illustrate the serious nature of their concerns. "On the day that was short-staffed with no one educated or trained to work the Olympus [chemistry instrument], which performs high com-

plexity testing, he [James Stewart] demanded that [name deleted], a high school graduate with no formal training or education in laboratory testing, run the Olympus and verify patient results. When she protested, she was told that her evaluation would be in jeopardy if she did not comply. He logged her on the computer and had her verify patient results under his log-on. He is also not trained on the instrument. There was no one in the Chemistry I lab that day trained to operate the instrument or verify patient results from the instrument."

That quote is from a memo sent by lab staff to hospital administration on July 25, 2002. Another example from the same document: "Please refer to the recent CAP survey C-B 2002 which failed not only Lithiums, but the entire survey failed. Twelve CAP survey specimens that failed were outside of three standard deviations [SD] and one was outside of 10 SD. All of the Lithium controls fell outside 5 SD or above. Considering anything outside of 2 SD is a concern and the farther away from 2 SD the more serious, you can see how troubling this is. It further supports the argument that [name withheld] was not monitoring the controls. ...all of this suggests that patients' results that were verified and used to diagnose and treat patients are unquestionably suspect."

LABOTECH's Failures

In April, THE DARK REPORT detailed the laboratory's problems with an instrument used to run infectious disease tests. It was the **Adaltis** LABOTECH. Acquired as a refurbished instrument, it was in clinical service from June 2002 through August 2003. Maryland DOH officials have determined that HIV and HCV test results produced during this time were released, despite the fact that the laboratory knew this instrument was producing unreliable results.

Some comments about the LABOTECH problems illustrate the deeper flaws in the operational structure of this laboratory The next group of comments come from a letter written by the former Chemistry II Lead Tech at MGH to the hospital, government health officials, and the local Congressman. It is dated March 31, 2004. "June 17 2002 thru July, 2002...Reagent validation studies [on the LABOTECH] continued to fail. The instrument continued to malfunction. All kinds of errors, mis-pipetting, mis-steps, probe crashes, arm errors and many more. the machine was a lemon and once [it was] on site, we found that it really did not accommodate our testing platform. It took longer from start to finish to complete a test than performing the test using the manual method."

Failed Validation Studies

Another example: "August 12, 2002... a directive was given to the Techs to do the Hepatitis B testing on the LABOTECH even though the LABOTECH had failed the validation studies. ...Patient results went out on the failed validation studies on the LABOTECH August 8, 14, 15, 2002. ...these patient results were intentionally tested and reported out on a failed instrument with full knowledge by Jim Stewart that they were unacceptable."

The next quote illustrates how med techs were specifically directed not to disclose these types of problems to state health inspectors (coming on site in response to complaints by the lab staff). This is also from the March 31, 2004 letter. "August 12, 2002: After the hospital and the state received the letters of complaint, everyone was scared. After that, I heard that the State would be coming in to investigate and that the problems would finally be addressed, corrected and all the information would be provided them to

make the necessary changes. We all knew that once the State saw all the evidence, the hospital would be made to contact the patients and doctors and correct all the problems."

But the state's inspection of the lab did not uncover these problems. The writer continues "October 31, 2002. I received a panic call from several employees that the State had made a surprise visit and that Stewart told everyone 'do not say anything that would jeopardize the hospital.' What does that mean? If anyone were to tell the truth about what was going on at Maryland General Hospital, that would in fact jeopardize the hospital? So what were they supposed to say when questioned? Out of fear, they remained silent."

Lab Techs Publicly Blamed

Earlier in this same March 31, 2004 letter, the writer references recent newspaper stories on the lab's problems and states that "only one side of the situation [is] being revealed to the public [and that] is frightening. ... Maryland General Hospital has its own Watergate, here and now. ...What we have here is a flood of cover-ups. The hospital has decided to blame it on the folks at the bottom of the food chain, the technologists. The technologists work under the direct supervision of the Lab Director. We were all under the total and complete dictatorship of Jim Stewart. We were told what to do and how to do it. When we voiced our concerns we were told by Jim Stewart it was 'none of our damn business'."

She continues "...this country encourages whistleblowers to come forward... But when we did come forward, we were labeled as troublemakers and were targeted by our employer with threats of retaliation. ...As employees with little influence, we sought help through the hospital chain of command. They too failed us."

THE DARK REPORT provides these quotes for two reasons. First, they graphically illustrate the range of problems in the laboratory, as told by the laboratory staff in their own words. Second, these quotes aptly describe the fundamental problem found within the walls of the laboratory at Maryland General Hospital. That was the failure of lab management and of the hospital management to acknowledge and fix the problems identified by the laboratory staff.

As reported in the *Baltimore Sun*, government lab regulators and hospital administration repeatedly identified the LABOTECH instrument as the "primary source" of the inaccurate test results reported to several thousand patients. Experienced laboratorians know this is a misrepresentation to whitewash the real reasons behind this sordid affair.

This lab's failures are directly attributable to the unwillingness of administrators to do the right thing. Thus reticence to act was reinforced by the corporate culture within Maryland General Hospital. Obviously hospital administrators and managers did not feel they would be supported if they tried to "do the right thing."

Techs Publicly Blamed

Quotes from memos and letters reproduced on these pages demonstrate these facts. Med techs in the laboratory complained that it was understaffed. Moreover, understaffing was significant enough that the laboratory director was willing to order an employee—who had no technical laboratory training—to operate a chemistry instrument and report the results using his (the lab director's) log-on ID.

Not only is this laboratory director willing to accommodate the corporate culture by operating an understaffed (as well as improperly staffed) laboratory, but he is willing to order a non-technical employee to perform clinical

Maryland General Hospital Lab Accreditation For Chemistry and POCT is Pulled by CAP

CRITICISM OF THE LABORATORY INSPECTION process as it took place at the laboratory of Maryland General Hospital brings unwelcome attention to the accreditation program operated by the **College of American Pathology** (CAP).

Late in April, the Maryland Department of Health (DOH) squeezed CAP. It requested to see the inspection and accreditation report of the MGH laboratory filed by CAP inspectors after their April 2003 site visit, when they had rated the troubled laboratory as "Accredited with Distinction." Initially CAP refused, stating that the College did not have a relationship with the state of Maryland.

Surprised by CAP's response, Maryland Health Secretary Nelson J. Sabatini responded, "So we told them, if they won't release their report, then we won't accept their certification." He then went on to say that state inspectors would assume responsibility for laboratory inspections. Sabatini then sent a letter to CAP stating that the Maryland Department of Health (DOH) would revoke the current accreditation of all Maryland laboratories inspected by the College of American Pathology. That would involve more than 120 labs in the state.

Faced with Maryland's challenge, CAP quickly backtracked on its position. It made the accreditation report available to DOH. It then conducted a re-inspection of the MGH laboratory on April 26, 2004. In a press release issued May 3, the College stated that "after thorough investigation of the issues, the College has determined that what caused the errors [in the accreditation process at MGH] appears to be the deliberate data manipulation by laboratory employees. The employees edited the quality control reports of the testing instrument used. This action caused unreliable patient results to be released and concealed MGH's problem from the CAP and the state of Maryland laboratory inspectors."

Based on the April 26 re-inspection and based on a "review of pertinent information regarding this laboratory and its compliance with the Colleges Standard for Laboratory Accreditation, the College has decided to suspend accreditation of the laboratory's chemistry and point-of-care testing services for a 30-day period beginning April 26, 2004."

testing duties that violate every tenet of laboratory operations.

Another failing was in quality control/quality assurance. The MGH corporate culture would not allow the laboratory to acknowledge that the purchase of the refurbished LABOTECH instrument was a mistake. But more significantly, lab administration was willing to put that instrument into clinical use before it was validated and begin to report patient results from that unvalidated instrument.

This lab director's actions speak volumes about the corporate culture and the willingness of clinical administrators in the hospital to bend established procedures for quality control. This, despite the fact that they knew, from their training and experience, that such violations could negatively affect patient care.

Moreover, the operation of this malfunctioning LABOTECH instrument led to a lab accident that exposed the med tech operating it to HIV and HCV. Months later she tested positive for both diseases, was the whistleblower who finally got the state to pay closer attention to this lab's problems, and is suing the hospital, the lab direc-

Med Techs' Cry for Help Goes Unanswered

ONE COMPELLING ASPECT OF THIS STORY involves the laboratory staff at Maryland General Hospital. It is unquestioned that med techs in this laboratory recognized the problems and took repeated steps to go through the chain of command.

This included formal communications and meetings with senior laboratory administration, formal communications and meetings with hospital HR and other administrators, and communications and/or complaints to the Maryland Department of Health (DOH).

It is remarkable that, for at least two full years, ongoing and regular efforts by this dedicated and sincere laboratory staff failed to get the full attention of people in positions of responsibility. Because some of these med techs documented and kept records of their efforts, they have credibility in describing their version of events.

Getting no response from lab administration, they next appealed to hospital administration. Finding no interest there, med techs then sent communications to the department of health. However, DOH inspections which resulted from these complaints failed to find the smoking gun. Why? Because lab administration cowed the med techs into silence while DOH inspectors were in the lab.

The unpublicized secret in the MHG lab failure is that the group that suffered most were those staffing the laboratory. Every day for more than two years they were asked to violate the basic tenets of their training. They were asked to ignore operational failures which were generating questionable laboratory results. They knew the potential human cost of these failures, yet were reprimanded and threatened with loss of their jobs if they told the truth and blew the whistle. The Maryland General Hospital laboratory disaster is a reminder that any system—and any laboratory—is only as good as the people who operate it.

tor, and Adaltis for causing her exposure to both life-threatening diseases.

What is most troubling is the failure of laboratory administration and hospital administration to place patient safety first. After 14 months of use, the decision was made to unplug the LABOTECH because it was delivering unreliable results. Yet no individual at either level of administration was willing to go back and address these failings with the patients who would be affected by inaccurate lab test results.

Unreliable Test Results

Here is a case of knowingly generating unreliable test results—for diseases that would negatively impact not only the patient, but other family members and people with whom they come in contact. There are plenty of court cases where a patient, knowing he/she was infected with HIV or AIDS, deliberately infected others by hiding this fact. If that was a criminal act in such instances, is it any less criminal for a laboratory administrator—and its hospital administration—to knowingly allow individuals who might be positive for serious disease to continue in society, acting on the basis of a laboratory test result that is known to be unreliable?

This is an ethical and legal question few lab managers and pathologists have to answer. That's because their laboratory performs to a high level of accuracy. Everyone has a high level of confidence in the accuracy of the test results they report to physicians and patients. Moreover, most laboratories have a working environment that encourages laboratory staff at all levels to come forward if problems are suspected.

That's what makes the serious problems inside the laboratory at Baltimore's Maryland General Hospital such a rare event. As a lab management case study, it demonstrates how quickly an unsound management culture can corrupt an entire institution. TDR

Lab Industry Briefs

HEALTH LINE CLINICAL LABS SIGNS $10 MILLION FRAUD SETTLEMENT WITH FEDS

DESPITE THE EVIDENCE that packing unnecessary tests into test panels is not acceptable to Medicare and Medicaid authorities, some laboratories continue the practice.

Health Line Clinical Laboratories, Inc. (HLCL) of Burbank, California is the latest lab company to pay a significant fine to settle allegations of Medicare/Medicaid fraud and abuse. On April 21, 2004, the United States Attorney for the Northern District of California announced a $10 million settlement with HCL and its owners, Aramis Paronyan, M.D. and Netalee Lalabekyan. Lalebekyan is married to Paronyan.

Starting in January 1, 1996 through September 20, 2003, HLCL was accused of adding five tests to "comprehensive panels and profiles that were ordered by physicians from HLCL." The tests added were apolipoprotein A & B, 5' nucleotidase, zinc protoporphyrin, and extractable nuclear antigen tests. Medicare and Medicaid investigators stated these tests were "medically unnecessary."

This settlement was triggered by a whistleblower lawsuit. The *qui tam* lawsuit was filed by Kim Jenkins and Timothy Mills. Both are former sales representatives from HLCL. Jenkins and Mills filed their lawsuit on January 30, 1998 in Federal District Court. Federal prosecutors formally joined the *qui tam* lawsuit on October 22, 2001 and filed their own complaint on December 17, 2001.

Jenkins and Mills will receive 20% of the $10 million settlement, or $2 million. As defendents, HLCL, Paronyan, and Lalebekyan will pay $160,000 for expenses and legal fees of the whistleblowers.

Health Line Clinical Laboratories has also signed a corporate integrity agreement with the Medicare and Medicaid programs. As a result of these concessions, federal prosecutors will not seek revocation of HLCL's license to provide lab testing services to the Medicare and Medicaid programs.

HLCL has been a fast-growing laboratory in California. It was formed in the mid-1990s, during the time when managed care pricing pressure was greatest on laboratories. HLCL's annual revenues are estimated to be around $35 million.

CHROMAVISION LAUNCHES MAJOR RESTRUCTURING, RAISES $21 MILLION

MAJOR CHANGES ARE UNDER WAY at **ChromaVision Medical Systems, Inc.**, the manufacturer of a cellular imaging system used by anatomic pathologists.

The company, based in San Juan Capistrano, California, raised $21 million by selling additional stock to a "limited number of accredited investors" last month. ChromaVision stock is publicly traded on NASDAQ under the symbol CVSN.

ChromaVision's primary product is the ChromaVision ACIS® (for automated cellular imaging system). In recent years, it has sold this system to anatomic pathology groups. ACIS uses "unique patented technology that detects, counts, and classifies cells of clinical interest based on color, size and shape to assist pathologists in

making critical medical decisions." The system has met with limited clinical acceptance since its introduction.

In response to the tepid market demand for the ACIS instrument system, ChromaVision is undergoing a major shift in its strategic business direction. The company will no longer sell ACIS instruments to pathology groups and laboratories. It is planning to establish its own laboratory and perform those clinical procedures for which the company feels ACIS provides a clear diagnostic benefit.

As ChromaVision implements this new strategy, it will be creating a new business model in anatomic pathology. The company has watched the growth of **IMPATH, Inc.** and **US Labs, Inc.** during the past decade. Its own business model will incorporate what it considers to be the strongest elements of the IMPATH and US Labs business models.

CYTYC–TRIPATH WAR SHIFTS TO A NEW FRONT: QUEST DIAGNOSTICS

PROBABLY THE MOST RANCOROUS competition among lab industry vendors is the ongoing liquid prep Pap "war" between **Cytyc Corporation** and **TriPath Imaging, Inc.**

Both companies offer laboratories a test kit that uses a liquid preparation technology to produce a thin-layer Pap smear slide. Cytyc holds the largest share of the U.S. market in liquid prep Pap testing, for two reasons. One, Cytyc was first to market, offering its ThinPrep® test kit to laboratories several years before TriPath's SurePath™ received FDA clearance.

Second, Cytyc signed an exclusive agreement with **Quest Diagnostics Incorporated** prior to 2000. As part of this agreement, Quest Diagnsotics received favorable pricing from Cytyc, was issued warrants for Cytyc stock, and agreed to use only Cytyc's products during the life of the contract.

Recently, two things happened which will stimulate a change in the competitive status quo between Cytyc and TriPath Imaging. First, the original contract between Cytyc and Quest Diagnostics expired. It was renewed on different terms.

Second, on May 6, Quest Diagnostics and TriPath Imaging announced a non-exclusive contract. Quest Diagnostics will begin using TriPath's SurePrep kit and its PrepStain™ slide processor. Quest Diagnostics will also evaluate TriPath's FocalPoint Pap analyzer (formerly called the AutoPap™ system). FocalPoint is approved by the FDA to perform automated primary screening of Pap smear slides.

There are two other important aspects of the agreement. One is that both companies will work in tandem to educate physicians about the SurePath technology. This probably includes joint sales calls by reps from the two companies. This contract provision means that, along with Cytyc's ThinPrep Pap test, Quest Diagnostics is now willing to educate physicians about other Pap testing options besides ThinPrep.

Second, the agreement includes a provision for TriPath Imaging to issue common stock warrants to Quest Diagnostics. Quest Diagnostics can also earn additional incentive warrants as it achieves specific milestones. Together, these contract provisions provide a important financial incentive for Quest Diagnostics to increase the volume of TriPath SurePrep testing it performs.

Because Quest Diagnostics does as many as 15 million Pap tests annually, it is in a position to squeeze lower prices and other concessions from both Cytyc and TriPath Imaging. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Oncology is predicted to be a major driver in laboratory testing in coming years *(see TDR, March 15, 2004)*. That said, lung cancer may be the next high-profile target, joining breast and prostate cancers as a high-priority disease. Last month the *Journal of the American Medical Association* (JAMA) reported that lung cancer rates among women have soared. It now kills 20,000 women per year, more than the combined deaths from breast and ovarian cancer.

MORE ON: Oncology

Maybe Thomas A. Scully shares the view that there is a bright future for companies offering diagnostic and clinical services in oncology. Since leaving his position as Administrator of the **Centers for Medicaid and Medicare Services** (CMS), he has become a Senior Advisor for **Welsh, Carson, Anderson & Stowe**, the private equity firm. Welsh Carson owns **Ameripath, Inc.**, holds equity in **Lab*One*, Inc.**, and just paid $1.15 billion to take **U.S. Oncology, Inc.** private.

MEDICAL ILLITERACY AFFECTS 90 MILLION AMERICAN ADULTS

Direct access testing (DAT) has an interesting hurdle to overcome on its way to becoming a bigger phenomenon. Earlier this month, the **Institute of Medicine** (IOM) released a report stating that 90 million Americans are "medically illiterate." This is about half the adult population. Medical illiteracy contributes to misunderstandings between physicians and their patients that often leads to bad consequences and poor healthcare outcomes. The IOM's findings were confirmed by a separate study released last week by the **Harvard School of Public Health** and **Educational Testing Services**. In this study, researchers concluded that communication barriers sustain and increase disparities in healthcare within the United States.

ADD TO: Medical Illiteracy

New medical technology actually increases the illiteracy gap between physicians and patients. "This is not something for which you can be immunized," stated researcher Dr. David A. Kindig. The studies noted that medical illiteracy was not limited to people with poor English, lower incomes, and little education. New healthcare technology can suddenly make esoteric scientific concepts into commonplace medical terminology, challenging even college graduates who want to keep up. Laboratories and pathology group practices providing information and services directly to patients should keep in mind that medical illiteracy affects half the nation's adults. For that reason, it is recommended that all laboratory test reports and information offered to consumers should be written in simple language and should be easy to understand.

• Clients of THE DARK REPORT may want to check out the May 10, 2004 issue of *Forbes Magazine*. **Laboratory Corporation of America** Chairman and CEO Thomas P. Mac Mahon earned a mention as one of seven "best bosses." Over the past six years, he's averaged a salary of $6 million per year while delivering an annualized return of 42% to LabCorp's shareholders.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 7, 2004.

UPCOMING...

- ***New Hospital Laboratory Outreach Program Grows into a Regional Powerhouse.***
- ***The Great Divide in Molecular Testing: Anatomic Pathology Fights the Clinical Laboratory for Control.***
- ***Overlooked Advances in IVD Technology That Can Boost any Lab's Value-Added with Physicians.***

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