Volume XVI, Number 6 Monday, April 27, 2009

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

A Global Flu Emergency

Next comes our intelligence briefing on the chaos unfolding in Mexico. Its inhabitants are reacting to the news that patients usually considered less vulnerable to influenza—young and mid-adult aged individuals—have died. What was originally classed as "atypical pneumonia" now has been identified as influenza virus A/H1N1. This is a new combination of genetic material from human, pig, and bird flu strains. It was just last Friday that the CDC issued its first public alert about the threat posed by this new form of influenza. By Saturday, the **World Health Organization** (WHO) was cautiously characterizing the known outbreaks in Mexico and in two U.S. border states as a "public health emergency of international concern." *(See pages 7-8.)*

However, health officials are privately discussing the possibility that, because containment is unlikely at this stage, there continues to be the potential for A/H1N1 influenza to evolve into a pandemic. As a challenge to clinical labs in the United States and across the globe, the emergence of A/H1N1 is another reminder—like SARS in 2003—that virulent diseases remain an ever-present threat to public health. Physicians who must diagnose and treat patients with these new diseases rely on accurate reliable laboratory testing. In turn, that is a reminder that laboratories should never betray the public trust. TDR

Puzzling New Flu Strain Causes Concern in Mexico

WHO, CDC, other health agencies take action to understand the never-before-seen A/H1N1 virus

CEO SUMMARY: In recent weeks, health authorities in Mexico became aware of a new strain of influenza, A/H1N1, because of unexpected deaths from "atypical pneumonia." As early as April 19, the CDC had identified similar cases in Texas and California. By last Friday, WHO, Canada's PHAC, and the CDC had posted public alerts about this new form of influenza. All clinical lab directors and pathologists should stay current with announcements from the CDC and local public health labs.

LAST FRIDAY, THE NEW STRAIN OF INFLUENZA IDENTIFIED IN MEXICO in recent weeks became headline news. Public health officials describe this new strain as A/H1N1 and say it is a never-before-seen combination of human, pig, and bird strains.

THE DARK REPORT was the first laboratory publication to inform its clients and readers of this fast-breaking news story. A *Dark Daily* e-briefing was released late Friday afternoon, just hours after the **Centers for Disease Control and Prevention** (CDC) issued its first public statements about this new strain of influenza, which the media calls "swine flu" because a significant amount of its genetic composition is similar to the known swine flu strains.

To bring laboratory directors and pathologists up to speed on this important story, here are key facts:

Veratect, Inc., of Kirkville, Washington is a company that monitors disease outbreaks on behalf of its clients. It says that it was first to identify that an unknown strain of the influenza virus was likely the cause of a patient death in Vera Cruz, Mexico, on April 6. It reported this finding to several public health organizations, including the CDC.

Between April 6 and April 24, Mexico identified cases of what its health officials described as "atypical pneumonia" and late-season influenza in several states, including Distrito Federal, San Luis Potosí, Baja California, and Oaxaca. Through April 24, Mexico identified 20 deaths from A/H1N1, was investigating another 40 deaths suspected from the same case, and reported 943 cases nationally of this new strain of flu.

Eight Confirmed Cases In U.S.

Also as of Friday, April 24, the CDC reported eight confirmed cases of swine influenza in the United States. Two cases were in San Antonio, Texas, and six cases were in the California counties of Imperial and San Diego. CDC said that preliminary genetic tests identified the cases as swine influenza A/H1N1 and that these cases were genetically similar to cases identified in Mexico. The CDC confirmed some of these cases as early as April 19.

Illnesses in Mexico were reported to be more severe than they were in the United

States, where, as yet, no deaths are attributed to this strain of influenza. CDC received 14 specimens from Mexico, and seven were positive for swine influenza A/H1N1.

In Canada, on April 22, the Public Health Agency (PHAC) put quarantine services on alert for travelers returning from Mexico with influenza-like illness (ILI). Public media announcements commenced on that date. The CDC received 51 specimens from Canada and 16 were positive for swine influenza A/H1N1.

So far, the United States has not reported deaths from the new swine flu. Last Friday, the *New York Times* reported that, of infections identified in the United States, "Five of the people infected were in Imperial and San Diego Counties in California and two were in San Antonio. They were 9 to 54 years old. None had any contact with pigs, and in two sets of cases—involving a father and daughter and two 16-year-old schoolmates—those infected had contact with each other. That convinced the authorities that the virus was being transmitted from person to person. The seven people were apparently infected from late March to mid-April. Only one was hospitalized, and all recovered."

U.S. Officials Go On Alert

Investigating the outbreak, the CDC sent staff to California, Texas, and Mexico. At border crossings and international ports of entry into the United States, enhanced surveillance was instituted. On Friday, the CDC was collaborating with officials from WHO, Canada, and Mexico, and seeking to characterize the severity of the clinical illness and the viral agent while also developing a communication strategy.

Even as public health authorities are working on a common response, the 24-hour cable news channels have begun showing video clips of how residents of Mexico are responding to news that a new strain of influenza has been identified. There are early signs of widespread consumer concern in Mexico. For example, last Friday, officials in Mexico City and suburbs suspended classes for all students, from nursery school to university level. At least six million students stayed home on that day. A further ban on most public events in Mexico City—including soccer matches—was announced over the weekend.

Informador, a Mexican news bureau, reported Friday that medical students at the **San Luis Potosí Autonomous University** (UASLP) were staying away from the **Central Hospital** in that city. The medical students were concerned about the "untypical pneumonia" cases and the risk of infecting their families and friends. There have been four fatal cases in San Louis Potosí.

Containment Not Likely

Privately, experts at WHO and CDC are saying that containment of this outbreak may now be impossible. There are about 1,000 people infected in at least 14 of Mexico's 32 states. Surveillance efforts by public health officials were only intensified less than a week ago.

It may also be too late to try and contain the spread of this new virus in the United States. One epidemiologist observed that no direct contact is known between the two cases in San Antonio and those cases in the San Diego area. That raises the possibility that the virus was spread between these two regions by other undiagnosed carriers of the virus.

Clinical laboratory managers and pathologists should develop strategies and response protocols to this situation. Close communication with public health agencies and the CDC is also recommended.

THE DARK REPORT and sister publication *Dark Daily* will continue to track unfolding events. Clients and readers are encouraged to contact our editors with useful new information or insights about influenza strain A/H1N1. TDR

Competitive Bidding Update

San Diego Labs Pursue Return of Bids from Medicare Officials

HAVING WON a significant court ruling last spring that stopped the Medicare Laboratory Testing Competitive Bidding Demonstration Project dead in its tracks, three San Diego-area laboratories are scheduled to return to court today. Important legal issues still need resolution.

At today's scheduled hearing, the three plaintiff laboratories—**Sharp HealthCare**, **Scripps Health**, and **Internist Laboratory** of Oceanside, California—will present arguments to amend their existing complaint. The labs seek to have the federal **Centers for Medicare & Medicaid Services** (CMS) return the bid information submitted by these labs last year.

In a ruling on March 25, Federal Judge Thomas J. Whelan dismissed the plaintiffs' lawsuit. At the same time, Whelan also denied the government's motion to dissolve a preliminary injunction he granted in April 2008 that prevented the federal government from implementing the lab testing competitive bidding demonstration project that was scheduled for implementation beginning on July 1, 2008.

Injunction Remains in Place

In his March 25 ruling, Whelan said he would dissolve the preliminary injunction unless the plaintiff laboratories file an amended complaint by April 27. At the same time, Whelan has urged the parties to resolve the dispute themselves.

"Judge Whelan actually gave us a very good ruling by keeping the preliminary injunction in effect until we can amend the complaint or work out something with CMS restricting CMS' use of the bid data—which we are trying to do," commented Patric Hooper of **Hooper, Lundy & Bookman, Inc.**, in Los Angeles, California.

In January 2008, Sharp, Scripps, and Internist Laboratory sued Michael Levitt, the former secretary of the U.S. Department of Health and Human Services (HHS), claiming HHS had failed to comply with the Administrative Procedure Act (APA) by imposing the competitive bidding demonstration project on the Metropolitan Statistical Area (MSA) in San Diego. The labs said that if they were not named the winning bidders, the competitive bidding project would cause irreparable harm to them and to the physicians and patients they serve. *(See TDRs, December 31, 2007, April 14, 2008.)*

Plaintiffs Want Bids Returned

Whelan's preliminary injunction effectively stopped the project from going forward, but those labs seeking to be winning bidders had already submitted bids to CMS. Since the project was halted, the three plaintiff labs have requested the return of the competitive bidding information so that CMS cannot use the data against them. Hooper argued that CMS could use the bid pricing information to set lower Medicare reimbursement rates, thereby achieving one goal of the competitive bidding demonstration project.

Last summer, the U.S. Congress permanently repealed the competitive bidding demonstration project for clinical laboratory services when it passed the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. TDR

Achieves 73% Fewer Deaths from CAD!

Kaiser in Colorado Uses Lab Test Data to Improve Cardiac Care

➤➤ CEO SUMMARY: Proud of a 73% reduction in mortality among patients with coronary artery disease (CAD) at Kaiser Permanente Colorado, clinical care teams there demonstrate how integrated care and more effective use of laboratory test data can lead to remarkable improvements in patient outcomes. Key themes in this achievement are the combined use of an extensive electronic health record (EHR) system and disease registries to give providers instant access to patient information, including real time access to patients' laboratory test results.

IT'S A POWERFUL DEMONSTRATION of how disease management programs can improve care for patients with chronic conditions. **Kaiser Permanente** Colorado reports a 73% reduction in cardiac mortality for patients in a comprehensive heart disease management program.

There is good news for clinical laboratories as well. Laboratory test data played a key role in the success of this effort. To achieve these outcomes, Kaiser used team-based care, medical best practices, and computer-generated care registries.

Kaiser Colorado's clinical care teams are supported by information in an electronic health record (EHR) system, which allows providers to have instant access to patient information. One of the most critical components of the data in the EHR and in the care registries are laboratory test results.

Moreover, the laboratory's ability to offer both speedy turnaround times and real-time electronic reporting of lab test results in Kaiser's EHR played a significant role.

Given that Kaiser Permanente is an integrated delivery system, its Collaborative Cardiac Care Services (CCCS) program offers an example of how health systems will use data—including lab test results—to manage patient care in the future and possibly in a reformed health care system. Given the success of Kaiser's CCCS program to substantially reduce mortality for patients with coronary artery disease (CAD), it is possible that the program could serve as a model for how health reformers may want to redesign the healthcare system in the future.

"Technology itself cannot solve the healthcare crisis," said George C. Halvorson, Chairman and CEO of Kaiser Permanente. "Our Colorado region achieved quality care results by aligning people and technology in the most efficient care delivery system. It was not newer or more expensive treatments, but an integrated approach to deliver the right care at the right time. Maximizing information for the clinician means optimizing care for the patient. As Congress and the President engage on healthcare reform, we must focus on the need to change the way we deliver care."

In exclusive interviews with THE DARK REPORT, lab managers and others involved in Kaiser's CCCS program explained how the disease management system works. At every step, laboratory test results play an important role in helping providers manage cardiac patients with chronic conditions.

➤LIS Interface To The EHR

Sharon A. Minor, a medical technologist and Senior Manager for Medical Office Laboratories, explained that healthcare providers order lab tests directly in Kaiser's EHR system, called HealthConnect. "When physicians or clinical pharmacists order lab tests in the medical record, that information goes directly across an interface to our laboratory information system (LIS)," she said.

"These lab test requests are immediately downloaded," continued Minor, "When the patient comes into a medical office to have his or her blood draw, specimens are collected and sent to our central laboratory.

"Our central lab receives the specimens and performs the tests," she stated. "These lab results are immediately transmitted through that same interface from our LIS to the patient's online EHR.

"If that Kaiser member is signed up to have access to portions of his or her EHR—and many of our members are—then that patient can look up the results," noted Minor. "Many test results are available on the same day. For routine tests, our turnaround times are usually under six hours."

Kaiser's EHR, HealthConnect, and HealthTrac, a disease tracking system used by CCCS, both play essential roles. When a patient is due for specific laboratory tests, HealthTrac identifies patients that are due for lab checks and a letter is sent to the patient. Patients normally then visit their Kaiser physician's office, where the specimens are collected, and then reported into the EHR.

"When the patient presents his/her name and Kaiser card at our physician's office, the staff checks the LIS to see what lab tests are

ordered," Minor said. "Because those tests are automatically ordered in the lab information system, the staff can print out the labels for the tubes right there. Couriers bring the specimens to our central lab."

Running Cardiac Lipid Panels

Michael Sheehan, Ph.D, a clinical chemist and Technical Operations Manager of the lab, explained that, "for the CCCS program, we run the usual cardiac tests, such as a standard lipid profile. We recently added a highly sensitive CRP (c-reactive protein) test. Since becoming available about five years ago, it has become an important way to assess for cardiac risk. In the past 24 months, physicians at Kaiser are using it more frequently.

"Like many automated laboratories, our lab is a fully integrated system," noted Sheehan. "For most routine testing, pre-accessioned specimens go right on the automated line. Once lipid specimens reach the chemistry analyzer, results are ready in about 10 minutes. If the laboratory test results are normal, they flow right into the patients' chart in Kaiser's Healthconnect EHR."

"The CCCS program follows more than 12,000 patients," observed Minor. "This program is a large driver of our lipid screening. In the anticoagulation program, there are about 7,000 patients on warfarin therapy.

Anticoagulation Service

"Another branch of the pharmacy department runs the anticoagulation service," she added. "It monitors warfarin therapy for these patients. In the laboratory, we partner closely with those clinical pharmacists to provide timely and accurate results for INRs (international normalized ratio tests). This permits them to make adjustments to patients' warfarin doses almost in real time. Our laboratory typically reports these results the same day that the patient had blood drawn.

"In addition, several smaller illness prevention and disease management programs focus on diabetes care, weight management, and colorectal cancer screening," Minor explained. "Over the past year, we worked with our prevention department to improve colorectal cancer screening rates.

"To do so, we introduced a new laboratory fecal immunochemical test (FIT)," she stated. "The benefit for us is that the test is more sensitive and easier to interpret than the older stool guaiac test, and for the patient, it is much easier to collect.

"Use of the FIT helped us identify a number of cancers that previously would have gone undetected," added Minor. "A positive lab test result must be confirmed and patient follow-up requires a colonoscopy."

Integration Plays Key Role

"The fact that Kaiser Permanente is an integrated health system makes it possible to link all aspects of care and each member of the care-delivery team," explained Brian Sandhoff, Pharm.D., a Clinical Pharmacy Supervisor who manages patients in the CCCS program. "All facets of care are integrated seamlessly. For example, when I order a lab test and the patient goes to provide a specimen, I can be confident that lab results will post in the patient's EHR in a timely manner.

"The CCCS staff review the lab results and the EHR to identify any confounders that may be contributing to abnormal test results," he commented. "So integration is key for us. As an integrated health system, Kaiser has invested considerable resources to connect all aspects of care to a sophisticated health information system. Achieving a 73% reduction in mortality of cardiac patients, for example, is an outcome that could not be achieved without connecting each member of the team with this integrated access to information.

"Each of our clinical pharmacy specialists manages the care for about 850 patients," said Sandhoff. "All individual lab test results automatically post to our in-

Real Time Laboratory Test Data Contributes to 73% Reduction in Cardiac Mortality at Kaiser

USING A TEAM-BASED APPROACH TO CARE, Kaiser Permanente Colorado significantly reduced the mortality rate for patients with heart disease. Employing medical best practices and computer-supported care registries, teams of clinical pharmacy specialists and nurses have worked collaboratively with physicians to reduce overall mortality by 76% and cardiac mortality (meaning all deaths from heart events) by 73%!

Called the Collaborative Cardiac Care Services (CCCS) program, it is designed to coordinate the efforts of providers through use of electronic health information, providing instant access to patient information, and giving providers evidence-based clinical guidelines and protocols.

Improving outcomes for patients with coronary artery disease (CAD) was the goal of Kaiser's care teams. One tool was the creation of an electronic care registry. Recognizing the importance of early treatment and intervention, every patient who presented with CAD was enrolled in the CCCS program for both short- and long-term care. Using proven CAD risk-reduction strategies, clinical pharmacy specialists and nurses work collaboratively with CAD patients and their physicians to coordinate care. Activities such as lifestyle modification, medication management, patient education, laboratory results monitoring, and management of adverse events are all coordinated across a multifunctional team.

The program is driven by agreed-upon, consistent clinical care guidelines and protocols that are integrated into Kaiser Permanente HealthConnect, a decision-support tool that guides the care teams, at the point of care, as they follow more than 12,000 CAD patients in the program. Immediate access to reliable, evidence-based information at all points of care enables each care team member to support a given patient's care plan, encourage treatment adherence, and allow disparate care teams to coordinate care, regardless of setting.

Research shows that fewer than 20% of CAD patients are expected to survive 10 years after their first heart attack. The coordinated, evidence-based care, enabled by KP HealthConnect and an electronic care registry, increased that survival rate dramatically. It is estimated that more than 135 deaths and 260 costly emergency interventions were prevented annually, as a result of improved care.

In addition, Kaiser said the program achieved the following results:

- Patients have an 88% reduced risk of dying of a cardiac-related cause when enrolled within 90 days of a heart attack, compared to those not in the program.
- The number of patients meeting their cholesterol goal went from 26% to 73%.
- The number of patients screened for cholesterol went from 55% to 97%.

Kaiser also reports that 10% of all patients account for 80% of healthcare costs—and 75% of those costs are related to chronic conditions. CAD affects 80 million Americans and is one of the five top chronic conditions that drive most health care costs, Kaiser said. It is the leading cause of death in the United States. Poorly managed, CAD often results in hospitalization and early death.

basket. Currently 15 pharmacists follow more than 12,000 patients in the CCCS program. When a clinical pharmacy specialist enrolls a patient in the cardiac risk program, he or she will review the patient's profile and assess which lab tests are needed to give us the information useful for us to manage those patients.

"Using HealthConnect—the electronic medical chart—we order those lab-

oratory tests," he explained. "Thus, when the patient shows up, the laboratory already knows which lab tests to draw. When lab results are ready, they come to us in our in baskets in the EHR, regardless of which clinic the lab tests were drawn.

"Our clinical pharmacy specialists then assess each lab result," Sandhoff commented. "If needed, the patient will get a telephone call to discuss further interventions. Otherwise, the pharmacist generates a letter saying that the current lab results indicate everything is where it should be and the patient is welcome to call with any questions.

"If a patient needs to come back in six months, a date is entered in the tracking system that tells him/her that patient is due in six months," Sandhoff continued. "CCCS runs reports every month to identify which patients are due for tests that month. The pharmacy then sends reminder letters via the mail to alert patients who need to come in.

Pharmacy Tracks Lab Tests

"To keep track of all this information, our pharmacy developed a system—called HealthTrac—outside of the electronic medical chart," he added. "It's a database that we use to schedule appointments, to generate letters when patients are due for lab tests, and to do queries to let us know which patients have not come in for their tests. HealthTrac ensures that we properly follow up with every patient.

"For the past five years or more, about 97% have had annual cholesterol testing," Sandhoff said. "When a patient is overdue for his/her next laboratory test, we send a reminder letter. After a third letter goes out, our pharmacy technicians will call these patients to remind them about the services they need. Should a patient fail to respond to these reminders, they will get a letter from us every six months."

"All of these systems are useful only if the clinical staff is vigilant about reviewing the lab test results and other data in the electronic records," observed Sheehan. "Once the data gets to where it should be, the system would break down without the vigilance of the people looking at the data.

Vigilance Required

Sandhoff agreed that having staff who are vigilant about reviewing the results is one key to the program's success. "CCCS was created to be comprehensive cardiac care service that improved cardiac patient survival and we have achieved that goal," observed Sandhoff. "When a patient has a heart attack, he or she goes into the hospital, and then gets enrolled in the CCCS program within 90 days of that event.

"Our research shows that if that patient is enrolled in CCCS within 90 days of the event, we can reduce mortality by up to 89% by monitoring each patient and following up over the long term. From a patient care standpoint, this is a very desirable result," he added.

Clinical pathologists and lab administrators should take note of these achievements. A 73% reduction of mortality among patients with coronary artery disease is a remarkable outcome—and clinician access to real time laboratory test results played an important supporting role in Kaiser Colorado's CCCS program.

THE DARK REPORT notes that an effective electronic health record, fully interfaced with the laboratory information system (LIS), was a key resource in the success produced by the CCCS effort.

That is a reminder of why it is important for clinical laboratories to have a sophisticated and progressive informatics strategy. Clinicians can be more effective in making diagnoses and selecting the most appropriate therapies when they have ready access to a digital health record that contains all their patients' laboratory test data. **TDR**

Contact Sharon A. Minor at Sharon.A.Minor@kp.org or 303-404-4106; Brian Sandhoff, PharmD, at brian.g.sandhoff@kp.org or 303-326-7681.

Kaiser Uses Lab Data to Improve Efficiency, And Boost Its National HEDIS Rankings

WHEN IT COMES TO HEALTH PLANS that are effective at moving laboratory test data into patients' electronic health records (EHRs), Kaiser Permanente is at the leading edge, so declares John Moor, a consultant with **Chilmark Research** in Boston, Massachusetts.

Having real time laboratory test data in a patient health record can make a significant difference. Consultant Moore observed that, when a patient with an EHR that contains recent lab test results shows up in an emergency room (ER), the physician can proceed with treatment. By contrast, the patient who does not have an EHR may need a battery of tests before the ER physician can treat.

And here's the downside for the patient who does not have an EHR: That patient may have had those same tests done recently but the ER may lack access to those results at the point of care. Therefore, the patient waits while the doctor orders new tests, wasting time and raising costs needlessly.

Improved Patient Outcomes

While Kaiser Permanente recognizes that using EHR data in this way empowers patients and providers while improving patient outcomes, there is another important reason why Kaiser created a real time flow of laboratory test data in its EHR and also stores that lab data in its HealthTrac system. As an HMO, each year Kaiser submits health data to HEDIS (Healthcare Effectiveness Data and Information Set). HEDIS is a set of standardized performance measures designed by the **National Committee on Quality Assurance** (NCQAO) to help purchasers and consumers compare the performance of HMOs and PPOs.

Every year, *U.S. News and World Report* publishes its rankings of the nation's top health plans. HEDIS scores are a key component of those rankings. Kaiser Permanente Colorado currently is ranked as the top health plan in Colorado. It is ranked number 42 in the United States. The next closest Colorado plan was ranked number 72 in the United States.

For Medicare members, Kaiser Permanente Colorado ranked number 8 in the United States, and was first in Colorado. The next closest Colorado plan was number 58 in the United States, according to data from *U.S. News and World Report*.

Top Clinical Care Rankings

Furthermore, Kaiser Permanente Colorado consistently ranks among the top health plans in the nation in the specific areas of cholesterol screening, advising smokers to quit, and prescribing beta-blockers to cardiac patients.

Real time flow of laboratory test data directly into patients' EHRs is recognized as one reason Kaiser Permanente Colorado achieves improved patient outcomes, relative to peer health plans. "We've worked hard in our laboratory organization to improve turnaround times and support a variety of clinical initiatives," stated Sharon Minor, Senior Manager for Medical Office Laboratories at KP Colorado.

"What gives our laboratory test data extra leverage with physicians is that our health systems IT systems are tightly integrated and talk to each other," she continued. "Having an EHR with a bi-directional interface to our LIS is recognized as essential in helping our care teams achieve improved outcomes. When providers have access to the medical record and complete, up-to-the-minute laboratory test data on their patients, it makes a positive difference in patient care."

Why Wall Street Likes Histology Lab Business

➤Professional investors recognize opportunity for sustained growth in specimens, plus ample profits

➤➤CEO SUMMARY: Over the past two decades, investor-owned anatomic pathology companies captured significant market share from community hospital-based pathology groups while delivering profits to their owners. Despite the recent downturn in the economy, Wall Street believes histology laboratories remain an attractive investment for investors. Financial analyst Kemp Dolliver explains the reasons why professional investors remain ready to invest in anatomic pathology firms.

DURING THE PAST TWO DECADES, most private pathology groups failed to fully benefit from the emerging market opportunities in anatomic pathology (AP) services. That made it possible for private investors to jump in and launch new businesses that competed with community pathologists for specimens.

During these same two decades, a parade of companies entered the AP market. **Urocor, Inc.** (1992); **Dianon Systems, Inc.** (1994), **AmeriPath, Inc.** (1995), **Pathology Partners, Inc.** (1998—now **Caris, Inc.**); **US Labs, Inc.** (2000); and **CBL Path, Inc.** (2003) are examples of investor-funded anatomic pathology companies which were formed to compete for AP specimens.

All continue in business today, despite experiencing changes in ownership. Unlike the clinical laboratory start-ups of the 1970s and 1980s, only one of the above-named companies was started by pathologists or had a pathologist as a Chairman or CEO during its formative period.

Despite today's tough economy, Wall Street remains bullish on anatomic pathology as a lucrative business opportunity. To help pathologists understand why professional investors continue to see dollar signs in anatomic pathology, THE DARK REPORT interviewed a Wall Street insider.

Kemp Dolliver is a financial analyst based in Boston, Massachusetts. In recent years, he has closely tracked the market for AP and clinical laboratory testing services. "A change in Medicare reimbursement for surgical biopsy services has positioned pathology laboratories as an attractive investment," observed Dolliver.

➤Medicare And 88305 Price

"This did not happen overnight," he continued. "For example, in 2001 Medicare paid $88.38 as global reimbursement for Billing Code 88305," he explained. "This was split 50-50 between the lab which performed the technical component (TC) and the pathologist who diagnosed the case (professional component, or PC). That meant about $44 was earned by each provider.

"Today, in 2009, Medicare's global reimbursement is $103.87 for the biopsy," said Dolliver. "But the split is now $66.72—or 64% of that $103.87 payment—for histology services (TC), while just $37.15—or 36%—is paid for professional interpretations (PC).

Professional Investors Actively Funding Companies involved in Anatomic Pathology

SUSTAINED INTEREST BY PROFESSIONAL INVESTORS in anatomic pathology companies (AP) is demonstrated by the number of transactions that were funded in recent years.

Referencing a report issued by **Cowen & Company**, financial analyst Kemp Dolliver offered a list of 10 independent pathology laboratory companies that either: 1) received funding from venture capitalists to expand and/or consolidate; or, 2) announced plans to expand in the trade press. The list of acquisitions and expansions includes:

- Nashville-based **American Pathology Partners** received $75 million from **New Enterprise Associates**, a global venture capital firm. Some of these funds were used to acquire the histology labs owned by Denver-based **UniPath**, the largest pathology practice in the Rocky Mountain region.
- Florida-based **Aurora Diagnostics LLC** received $150 million since 2006 from two venture capital firms, Boston-based **Summit Partners** and New York-based **GSO Capital Partners**, to acquire 13 pathology practices.
- **Water Street Capital**, a Chicago-based private-equity fund, acquired New Jersey-based **Lakewood Pathology** in 2006 for $50 million, and last year renamed it **PLUS Diagnostics**. Some of the money went to expansion of lab facilities, to hire sales people, and to upgrade reporting systems.
- **Laboratory Corporation of America**, a publicly-traded company based in Burlington, North Carolina, acquired **IDX Pathology**, of Boise, Idaho, and **PathNet Esoteric Laboratory Institute**, of Van Nuys, California.
- **Bostwick Laboratories** of Richmond, Virginia, filed a prospectus as the first step of an initial public offering (IPO) last year. It then delayed its IPO due to conditions in the stock market.
- **CBLPath**, a laboratory company headquartered in Ocala, Florida, and backed by the New York investment firm **Galen Partners**, has retained an investment bank to evaluate strategic options to merge or sell.
- Southern California-based **Clarient**, part of publicly-traded **Safeguard Scientifics**, announced a $50 million investment from Connecticut-based **Oak Investment Partners** to expand laboratory biopsy services to meet the growing demand of outpatient oncology practices nationally.

Additionally, three laboratory firms announced plans to expand: Southern California-based **Pathology Inc.**; Augusta, Georgia-based **ClariPath** (a subsidiary of urology equipment supplier **Healthtronics**); and North Texas-based **Caris Diagnostics**, a national diagnostics laboratory services provider backed by the private investment firm **Caris Limited**.

"Investors recognize how the higher amount paid for technical services creates an incentive for pathologists to have a stake in providing both technical and professional services in order to bill globally for their services," Dolliver said. "That makes histology laboratories quite attractive to professional investors who could provide the capital for a laboratory. So, even as Medicare tightened up payments for professional services, related changes in TC reimbursement opened up a highly attractive business opportunity for pathologists."

Favorable Economics

"To take advantage of the favorable economics of histology laboratory services, investors formed or acquired laboratory

companies that either employ or partner with pathologists to compete for the biopsy referrals of office-based physicians," said Dolliver. "These investor-owned AP companies then become direct competitors to community hospital-based pathology groups which traditionally had a lock on biopsy referrals in their local community.

"Moreover, these investor-owned AP companies aggressively use sales reps, superior service, and, in some cases, lower prices to win new clients," added Dolliver. THE DARK REPORT notes that, in client-bill states, some investor-owned AP competitors will deeply discount their prices as a way to win new business from office-based physicians.

Dolliver offered another insight about why professional investors like anatomic pathology more than clinical laboratory testing. The anatomic pathology profession remains highly fragmented. Thus, it is ripe for the same consolidation that has occurred in other medical specialties. "Rightly or wrongly, investors view clinical pathology testing as more of a commodity business," he stated. "For example, a urinalysis involves little professional judgment because automated analyzers perform the test and report out a number that is easy for the referring physician to understand.

"On the other hand, investors see a different value proposition in the diagnosis of biopsies," he observed. "Investors consider pathologists to be highly-trained professionals who provide essential information in life-or-death situations. The point is that a pathologist's professional interpretation is less prone to commoditization, relative to highly automated testing of blood and urine samples.

"Of course, investors know they need pathologists to be part of these businesses," commented Dolliver. "Investors believe they bring several things to the table that have value to pathologists. First, as the lab increases specimen volume and revenue, pathologists can increase their incomes.

"Second, as the company expands its business regionally or nationally, pathologists get more income from the professional services they provide on the ever-increasing number of cases. Third, having investors run the operational and business development functions of the histology business offers pathologists relief from time-consuming administrative functions they dislike, including payroll, billing, collections, and sales and marketing."

Two Growth Drivers

Dolliver further noted that Wall Street recognizes two growth drivers that give anatomic pathology a bright future. One, demographic trends guarantee that the incidence of cancer and other diseases will increase and that will drive increased case volume for pathologists. Two, anatomic pathology is expected to play a key role in the practical application of genomics information and nanotechnologies for disease prevention, personalized medicine, and diagnostics.

"This is why turmoil in financial markets during the past year has not dampened investor enthusiasm for histology and AP services," stated Dolliver. "This sector continues to attract new investment and continues to consolidate. Those laboratories and pathology groups willing to take an entrepreneurial approach to expanding currently have no problem finding interest and backing from venture capitalists."

"I expect this trend will continue," concluded Dolliver, "as long as: 1) these companies offer pathologists an appealing work environment with competitive compensation; 2) the current reimbursement system remains in place; and, 3) the public markets and/or the industry's leaders (Quest Diagnostics and LabCorp) will value these businesses at attractive multiples of earnings. TDR

—Patricia Kirk

Contact Kemp Dolliver at 781-258-0240 or kdolliver@gmail.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

As unemployment rates climb in the United States, employers are ordering fewer pre-employment drugs of abuse (DOA) screening panels. This is expected. It is why investors know that drugs-of-abuse volumes are closely linked to the economic boom/bust cycle. During first quarter earning calls, public lab companies revealed the bad news in this sector of lab testing. **Quest Diagnostics Incorporated** reported that its DOA volume had declined about 25% from Q1-08. It was a similar story at **Laboratory Corporation of America**, where DOA volume declined 20.1% from the last year's first quarter.

MORE ON: Drug Tests

It was a mixed bag at **Medtox Scientific, Inc.**, of St. Paul, Minnesota. MedTox announced that drugs of abuse test volume had declined 14% compared to Q1-08. However, it also noted that "the decrease in [DOA] revenue was mitigated by very strong new business from laboratory drugs-of-abuse clients of $1.4 million, or a 14% increase from the prior-year period for a total of $8.4 million."

BEA ARTHUR AS MED LAB TECHNICIAN

Put this item in the category of "lab industry things you never knew." In covering the death of actress Bea Arthur on Saturday at age 86, an *Associated Press* reporter wrote, "After two years at a junior college in Virginia, she earned a degree as a medical lab technician [MLT], but she 'loathed' doing lab work at a hospital."

OBITUARIES

• Died on April 5, 2009, of cancer, Daniel M. Baer, M.D., Professor Emeritus, Department of Pathology, **Oregon Health and Science University** in Portland, Oregon. Baer was widely-known for his monthly column in *MLO Magazine*, titled "Tips from Clinical Experts," which he wrote for almost 20 years.

• Died on March 29, 2009, Ronald H. Laessig, Ph.D., Emeritus Director of the **Wisconsin State Laboratory of Hygiene** and Emeritus Professor of Population Health Sciences at the **University of Wisconsin Medical School** in Madison, Wisconsin. Laessig was widely-known for his contributions on national issues in laboratory medicine over four decades. With Sharon S. Ehrmeyer, Ph.D., Laessig co-authored *The New Poor Man's (Person's) Guide to the Regulations (CLIA '88, JCAHO, CAP & COLA).*

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd be among the first in the lab industry to know about...

...the outbreak of a new strain of influenza in Mexico, and how six cases of the same strain of flu were detected in Texas and California.

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

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 18, 2009.