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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Cerner Acquires Lab Automation Company

BY NOW, MANY OF YOU HAVE HEARD THE NEWS that **Cerner Corporation** has acquired **Labotix, Inc.**, the laboratory automation company based in Peterborough, Ontario. That transaction was announced last Monday, March 18.

I consider this deal notable because it is an example of how strange bedfellows will be joining forces as healthcare undergoes a radical transformation in the coming years. In this case, it is a health information company purchasing a company that manufactures laboratory automation systems. Traditionally, these have been viewed as distinct businesses without much overlap.

What is changing traditional thinking is the fundamental shift in healthcare away from a system of independent providers toward a healthcare system comprised of integrated clinical care organizations. Thus, in the same manner that hospitals, physicians, and ancillary providers are coming together in ACOs, medical homes, and the like, it is reasonable to expect that healthcare vendors may see logic and opportunity in bringing diverse products and services into their particular corporate umbrella.

The goal of these vendors would be to create an integrated product and service offering that better meets the needs of an integrated provider organization. In that regard, Cerner's acquisition of Labotix could be an early example of this corporate strategy. With its laboratory information system (LIS), Cerner holds significant market share, with hundreds of hospital labs as customers nationwide. For its part, Labotix has a total lab automation solution with task-targeted automation systems.

Could Cerner have a two-pronged strategy? One part would be full integration of its LIS with Labotix's lab automation software (LAS) and its lab automation equipment. Part two would be to then offer this tightly-integrated bundle of lab software and lab automation equipment to its hospital lab customers. In theory, Cerner would be able to sell this integrated bundle on the promise of greater productivity, improved reliability, and unmatched capability to monitor both lab workflow and the performance of instrument systems in real time.

Time will tell if the integration of clinical providers encourages health vendors to similarly integrate across traditional lines of manufacturing and service. That is a reason to watch for more unexpected pairings, like last week's acquisition of Labotix by Cerner Corporation. TDR

Anticipating Washington's Next Blows to Lab Testing

Even as laboratories react to reduced revenue from multiple cuts in lab prices, more is to come

CEO SUMMARY: With the advent of 2013, almost every lab was responding to some type of price cut. Clinical labs are dealing with the sequential, multi-year cuts to the Medicare Part B Lab Test Price Schedule. Anatomic pathology labs are still adjusting to the expiration of the TC Grandfather clause last summer, as well as the substantial reduction to Medicare fees for the 88305-TC CPT code that became effective on January 1. Some lab industry observers expect more price cuts this year.

DURING THE PAST 12 MONTHS, the clinical lab testing industry and the pathology profession have suffered multiple hammer blows to coverage guidelines and the level of reimbursement paid for certain lab test procedures.

These developments are having an immediate and negative effect on large numbers of labs in 2013. To survive, these labs must quickly cut expenses or find new sources of specimens that will be reimbursed at adequate rates.

Even as they scramble today to offset the revenue losses associated with recent coverage and price policies, they are casting a wary eye to the future. It should be no surprise, then, that lab administrators and pathologists are asking "What's next?"

At the inception of 2013, labs were dealing with the negative financial consequences from the expiration of the TC grandfather clause in mid-2012, the sequential multi-year series of cuts to the Medicare Part B Laboratory Test Fee Schedule, and the radical reduction to CPT code 88305-TC that became effective on January 1, 2013.

But the bad news is not limited to just these three examples of recent policy changes. There are other healthcare trends and market dynamics with the potential to disrupt the lab testing industry as it exists today. These trends range from hospitals and payers acquiring physicians' practices to the arrival of integrated clinical care as delivered by ACOs and medical homes.

To help lab managers and pathologists understand what is expected to come during the balance of 2013 and beyond,

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

THE DARK REPORT has arranged a number of special sessions at the upcoming 18th annual *Executive War College on Lab and Pathology Management*. This will take place on April 30-May 1, 2013, at the Sheraton Hotel in New Orleans, Louisiana.

Anticipating Future Events

One particularly unique presentation will bring together an exceptional group of experts. It is a two-hour panel titled "Big Changes Ahead in Federal, State, and Private Payer Policies Affecting Laboratory Testing Reimbursement and Regulation."

As the title implies, this is an up-to-the-minute understanding of events unfolding within Washington, DC, at key state capitals, and with private payers. The panelists include:

- Michael Arnold, Executive Director, **California Clinical Laboratory Association** (CCLA)
- Mark S. Birenbaum, Ph.D., Administrator, **American Association of Bioanalysts** (AAB)
- Andrew Fish, Executive Director, **Advanced Medical Technology Association, Diagnostics** (AdvaMedDx)
- Alan Mertz, President, **American Clinical Laboratory Association** (ACLA)
- John Scott (invited), Vice President, **College of American Pathologists** (CAP)

Each panelist is actively involved in educating elected officials, regulators, and health insurance executives about the value of laboratory testing services. This session will provide attendees with a solid understanding of the best and the worst of what is being proposed by legislators, regulators, and payers that affect the clinical practices and financial integrity of clinical laboratories and pathology groups.

However, these actions are not the end of the bad news for the profession of laboratory medicine. To the contrary, they can be considered the opening round in what some long-time lab industry observers believe will be a multi-year series of major policy changes and reimbursement cutbacks that will continually and consistently undermine the financial stability of lab testing organizations.

Take the example of the 104 new molecular CPT codes. Will the Medicare program and private payers establish reasonable coverage guidelines and equitable prices for these new CPT codes? There are already good and bad examples of pricing by the first few Medicare contractors to issue their respective policies for these molecular CPT codes. *(See TDR, March 4, 2013.)*

Even as you read this, different Medicare contractors are taking steps to post their prices for these molecular CPT codes. Charles Root, Ph.D., widely recognized as the founder and CEO of **CodeMap, LLC**, will provide a timely review and analysis of these developments at the *Executive War College*. He plans to share data and insights about molecular test pricing and the ramifications of the specific pricing published by Medicare contractors as of that date.

How ACOs Can Be Disruptive

Possibly the most disruptive development in healthcare today is the transformation to integrated clinical care. The best manifestation of this trend is accountable care organizations (ACOs). As reported recently in THE DARK REPORT, the consulting company **Oliver Wyman** of New York City estimates that, as of the end of 2012, between 25 million to 31 million patients were already affected by Medicare and private ACOs. *(See TDR, February 11, 2013.)*

In order for ACOs to deliver integrated clinical care, they are bringing different classes of healthcare providers into their organization. Included are hospitals, primary care physicians, specialist physicians, and ancillary service providers, ranging from skilled care facilities to physical therapy clinics.

Some experts predict that the clinical labs of hospitals and health systems that

are part of the ACO will have the inside track to provide lab testing to these ACOs. They also predict that the ACOs will move away from fee-for-service reimbursement for lab testing services.

Given the importance of the ACO trend, this year's *Executive War College* has scheduled many presentations by speakers who are fully engaged in either developing ACOs or providing services to the ACOs in their community.

ACOs Forming In Northwest

For example, in the Pacific Northwest, several Catholic health systems are coming together via consolidation or affiliation to create regional and supra-regional health systems. Ran Whitehead, CEO of Eugene, Oregon-based **PeaceHealth Laboratories**, will discuss how his lab, owned by PeaceHealth, is positioning itself to add value across the multi-state geography served by these health systems.

Similarly, Texas is a state where large health systems are scrambling to buy up physician groups and develop ACOs that offer competitive advantage in their home cities. Ernest Franklin, M.D., Vice President of Surgical and Ancillary Services at **Baylor Health Care System** in Dallas, will describe these developments.

Baylor Health & med fusion

Baylor Health is made up of 15 owned, leased, or affiliated hospitals and six "short-stay" hospitals. Baylor Health is also an investor in **med fusion**, a unique laboratory joint venture with a distinct vision and strategy for using lab testing to add value. Keith Laughman, CEO of med fusion, will speak about this new lab testing paradigm and why the lab joint venture includes pathologists and **U.S. Oncology** as investors. *(See TDR, March 8, 2010.)*

Given the uncertain times in the lab testing marketplace, the full range of topics and speakers at this year's *Executive War College* is designed to give lab administrators and pathologist business leaders, the essential insights and information they need to craft effective strategies to keep their laboratory organizations financially stable and properly positioned to respond to these market trends. TDR

Prepare for Powerful Trends That Change Lab Test Market

ACROSS THE NATION, laboratory leaders are telling the editorial team of **THE DARK REPORT** that their lab organizations are facing an unprecedented time of change. They can identify numerous powerful trends that are reshaping healthcare within their communities and their regions.

Here is a partial list of the more significant trends reported by these lab leaders. Each trend has the potential to change the status quo in laboratory testing.

- Price cuts to lab tests by government and private payers.
- Introduction of integrated care via ACOs, medical homes, and the like.
- Private payers narrowing and excluding local labs from their provider networks.
- Value-based reimbursement and bundled reimbursement arrangements for providers.
- Continuing adoption of EHRs by hospitals and physicians, with staged requirement to meet meaningful use criteria.
- New diagnostic technologies, ranging from next-generation gene sequencing to increased use of mass spectrometry in clinical testing.

Experts on each of these trends and developments will be speaking at the upcoming 18th annual *Executive War College*, to happen on April 30-May 1 in New Orleans, Louisiana. Full program and speaker information can be found at: *http://www.executivewarcollege.com*.

Lab Compliance Update

Mass. AG Coakley Cites Two Labs in 48-Count Medicaid Kickback Case

Alleges that local physician steered drug tests to labs in exchange for payment of staff salaries

Massachusetts Attorney General Martha Coakley has cited two lab companies in a case involving kickbacks related to drugs of abuse testing.

Coakley's office made the announcement on March 8. Coakley alleges that fees were collected from patients illegally and that prescriptions for medications were illegally issued to patients diagnosed with opiate addiction.

Four Defendants Indicted

Earlier this month, a Suffolk County grand jury returned 48 indictments against four defendants in what Coakley said was an "industry-wide independent clinical laboratory investigation" by the AG's Medicaid Fraud Division. Richard Ng, M.D., the former director of a drug abuse clinic in Brighton, was charged with 11 counts of illegal prescribing, nine counts of Medicaid false claims, and seven counts of Medicaid excess charges. The Medicaid kickback scheme was worth more than $590,000, the announcement said.

Coakley also charged **Franey Medical Lab Inc.**, of Mashpee with one count of Medicaid kickbacks, one count of Medicaid false claims, and three counts of private health insurance kickbacks.

Ng's former office manager, Renee Andrews, of Hudson, New Hampshire, was charged with four counts of Medicaid kickbacks, two counts of Medicaid false claims, and five counts of private health insurance kickbacks, the announcement said.

Allegedly, Andrews offered and entered into Medicaid kickback arrangements with two laboratories, Franey Medical Lab and **East Side Clinical Laboratory** in East Providence, Rhode Island, Coakley said. Her office did not report filing charges against East Side Clinical Laboratory.

Coakley charged Kathleen Franey-Lopes of Marstons Mills, with one count of Medicaid kickbacks, one count of Medicaid false claims, and three counts of private health insurance kickbacks. Franey-Lopes is the vice president of the lab and the daughter of Robert Franey, the owner of the lab, according to *The Cape Cod Times*. She was the primary contact with Ng's office in 2007 and 2008, Coakley said.

Labs Paid Salaries

Coakley charged that, in exchange for Ng's receiving urine drug screening business, the laboratories paid the salaries of some of Ng's office staff. The defendants will be arraigned on April 4.

Since 2004, Coakley has brought enforcement actions against at least five other laboratory companies that offered lab tests in support of pain management testing services. Coakley won settlements in each of these cases. *(See TDR, October 11, 2011.)* TDR

Labs Have Opportunity to ID Sepsis Much Faster

Innovations at one health system's micro lab contributed to improved outcomes, more revenue

CEO SUMMARY: In the Northeast, the microbiology department of a four-hospital health system adopted new technology for testing patients suspected of sepsis. Not only did this microbiology lab shorten the time-to-detection, it increased the diagnosis rate for sepsis from 9% to 15%—an improvement in detection of 67%! This effort led to shorter patient stays, improved patient outcomes, and the ability to code more accurately for sepsis, thus increasing revenue for the health system by $1.7 million.

AS LAB BUDGETS SHRINK, it becomes essential for pathologists and laboratory directors to demonstrate how clinicians can use clinical lab tests to deliver more value—in the form of improved patient outcomes and lower cost per healthcare encounter.

One opportunity for the hospital lab to deliver substantial added value is in the diagnosis and treatment of sepsis. Time to treat is the critical parameter for patients with sepsis because any patient showing signs of septicemia needs immediate treatment. To treat these patients optimally, clinicians need to identify the pathogen causing the infection so they can choose the most appropriate medication.

Even before they know which pathogen is causing the infection, physicians often prescribe a broad spectrum antibiotic. They do so because it typically requires many hours or days before the microbiology laboratory can definitively identify the infectious agent. These agents can include bacteria, yeast, and fungi. Of great concern is the fact that 35% to 70% of sepsis cases result in patient death.

At **New York Presbyterian Columbia University Medical Center** (NYP/CUMC) in New York City, the microbiology laboratory is implementing specific innovations to improve diagnostic accuracy and shorten the time-to-answer for patients suspected of having sepsis. To achieve this, the lab needs to develop solutions to address several unique aspects of the patient population it serves.

This effort is led by Susan Whittier, Ph.D., ABMM. She is the Associate Director, Clinical Microbiology Service at NYP/CUMC. "Having a positive identification of sepsis not only improves patient care," she stated, "but can also increase hospital revenue in ways that I will explain."

75,000 Blood Cultures Yearly

In the medical center's Clinical Microbiology Service, Whittier's laboratory is comprised of 50 technologists. They staff the service 24 hours a day, seven days a week. This microbiology laboratory analyzes more than 75,000 blood cultures annually from three hospitals.

Whittier's keen interest in sepsis testing started before she joined the staff at New

York Presbyterian/Columbia University Medical Center. Previously, Whittier worked in a four-hospital system in New Jersey. There she studied methods of sepsis testing that included the BAC TEC Plus Aerobic medium, a blood culture product from **Becton, Dickinson Diagnostics** (BD). During her years at this health system, Whittier found this culture medium to be more effective in helping clinicians to identify sepsis than other testing methods.

Whittier believes a clinical study published March 15 in the journal, *Clinical Infectious Diseases,* confirms her experience in New Jersey. Titled "Comparison of 2 Blood Culture Media Shows Significant Differences in Bacterial Recovery for Patients on Antimicrobial Therapy," it involved almost 9,400 blood cultures. *(See http://cid.oxfordjournals.org/content/56/6/79.)*

Early Results Confirmed

"This study is exciting because it shows the tremendous potential to identify—within hours—the specific infectious agents that are in a blood culture," she said. "One key finding from this study is that it shows the value of using resin as a medium versus non resin.

"For 15 years, clinical researchers have been using *in vitro* methods to demonstrate the benefit of resin," observed Whittier. "While *in vitro* data has consistently shown that the resin system is better than the non-resin system, clinical correlation was lacking. What is different about this study is the large number of patients, almost 10,000, and the use of clinical parameters that are different from those used in prior studies."

The new study shows how early treatment with broad-spectrum antibiotics can negatively affect clinicians' ability to detect bacteria in blood samples from potentially septic patients, according to a report on the study in *Infection Control Today.*

The research also demonstrated the importance of antimicrobial removal systems, such as the BAC TEC resin, to quickly and accurately detect the pathogens. In turn, this aids physicians in making treatment decisions about which therapies to use for patients suspected of having septicemia, *Infection Control Today* reported.

Significant Study Findings

"The fact that the resin-based system was fast and accurate at recovering bacteria from patients who were already treated with antimicrobials is significant," explained Whittier. "This is because many patients suspected of having sepsis often are treated with broad spectrum antibiotics before clinicians have a positive identification of the pathogen.

"At our hospital, located in the Washington Heights neighborhood of Manhattan, we regularly have a significant proportion of our patients show up at the hospital on inappropriate antibiotics," she continued. "Yes, this happens everywhere. But in this neighborhood, patients can get antibiotics over the counter from local bodegas. That is what happens in the Dominican Republic which is where our patients are from, so that's what happens here.

"Also, when patients suspect they have an infection, they may have antibiotics from an earlier prescription," noted Whittier. "Those antibiotics may or may not be useful to them by the time they arrive in our emergency department.

Antimicrobial Removal

"These are the reasons why these antimicrobial removal devices are so important to our microbiology department," she said. "Our laboratory needs to identify the pathogen regardless of what antibiotics the patient has been taking.

"We've made inroads at improving both the time-to-answer and the accuracy of diagnosing sepsis," she added. "This contributes to improved patient outcomes. It also helps add revenue for the hospital.

"It happens because, once the hospital has a positive diagnosis, it can bill for the

higher amount allowed under the DRG for sepsis," stated Whittier. "By contrast, if the case is coded as an 'infection of unknown origin,' the DRG is not as high and the difference can be several thousand dollars in lower reimbursement.

"While working with the four-hospital system in New Jersey, the microbiology department recommended replacing the routine media for sepsis identification with media containing the resin," she recalled. "However, the resin was a bit more expensive and we needed to justify the increased costs within the lab.

"The change in outcomes was rather dramatic," continued Whittier. "As a result of using the resin media at the four hospital labs sending samples to our core lab, we saw the positive blood culture rate increase from 9% to 15%! Then, to examine the financial effect of the increased blood culture rate, we looked at the DRG data.

Increased Rate Of Detection

"At three separate hospitals, the DRG coding for sepsis went up by 40% to 50% as a direct consequence of our microbiology laboratory identifying more positive blood cultures," she noted. "This had two measurable benefits.

"First, by providing clinicians with a faster and more accurate answer, the length of stay for sepsis patients was reduced," stated Whittier. "When clinicians had the correct diagnosis, they could treat these patients with the appropriate medication and get them home sooner.

"Second, revenue associated with the appropriate DRG for sepsis increased by about $1.7 million," she said. "That's significant. It demonstrated that spending a little extra for lab testing could deliver both improved patient outcomes and a favorable increase in the parent hospitals' revenues."

Since her arrival at NYP/CUMC, Whittier has laid the groundwork to launch a similar program. "We have implemented resin-based blood culture bottles here as well," observed Whittier. "As a bigger and more complex medical center, analyzing the data is a bit more complicated.

"However our initial review supports my past findings," she said. "Use of resins when testing for sepsis can optimize patient management, and the financial implications for the medical center are significant as well. It is a win-win situation for the patient and our bottom line." TDR

—By Joseph Burns

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More Attention on Sepsis Creates Lab Opportunities

SEPSIS IS THE MOST COMMON KILLER in intensive care units, according to experts on this systemic infection. The death rate from sepsis is higher than that of breast cancer, lung cancer, and stroke combined, according to one researcher.

Worldwide, hospitalizations for sepsis more than doubled in the past 10 years, according to the **European Society of Intensive Care Medicine** (ESICM). Our sister publication, *DarkDaily.com*, issued an e-briefing on February 11 on the action by New York State to implement tougher standards for the diagnosis and treatment of hospitalized patients with sepsis. Under the new requirements, which have yet to be published, physicians must become faster at making an accurate diagnosis of sepsis. This development was announced by New York Governor Andrew M. Cuomo in his State of the State message in January.

The New York Times reported that, once the regulations are published, New York will be the first state in the nation to require hospitals to take aggressive steps to manage patients suspected of having sepsis so that treatment can begin sooner. Hospitals in New York must adopt new procedures to identify sepsis, including using a countdown clock to begin treatment within an hour of diagnosis.

CEO SUMMARY: Mass spectrometry is a diagnostic technology that is transforming clinical labs and improving care at a rapid pace. The current generation of instruments is capable of supporting a faster time-to-answer and provides improved accuracy and specificity over many existing methods. For certain clinical assays, mass spec also can cost less per test than conventional testing methods. Advocates of mass spectrometry predict a bright future for its use in clinical diagnostics.

It's a fast-growing trend in both the United States and Europe

Mass Spectrometry Is Finding Larger Role in Clinical Labs

BY PRODUCING BETTER RESULTS faster and cheaper than conventional diagnostic methods, mass spectrometry is displacing long-established technologies.

In many ways, mass spec has a legitimate claim as one of the next "big things" to happen in laboratory medicine. In fact, advocates of mass spectrometry predict that, at some future point, this method may become the dominant mode of testing in many labs.

Further, these same experts acknowledge that, although molecular and genetic testing will have growing and important roles in laboratory medicine, it is mass spectrometry that is poised to assume a large share of the workload in clinical labs.

If this proves true over time, it means that the adoption of mass spec for a growing number of clinical diagnostic purposes will be one of lab medicine's essential trends. For these reasons, lab administrators and laboratory directors will want to be up-to-date on this rapidly-evolving technology.

"Already, mass spectrometry is becoming the pre-eminent technology in microbiology," said David A. Herold, M.D., Ph.D., Chief of Clinical Chemistry at the **VA San Diego Healthcare System** and a Professor in the Department of Pathology at the **University of California, San Diego**. "Because it can deliver critical time-sensitive test results in a rapid manner, mass spectrometry is shortening test turnaround times in the microbiology lab." *(See sidebar, "Houston's Methodist Hospital Uses Mass Spec To Foster Lab and Pharmacy Collaboration.")*

"Mass spectrometry allows clinical labs to get answers more quickly than can be obtained from conventional testing methods for many assays," Herold said. "When used appropriately, mass spec can significantly reduce the time needed to identify pathogens compared with more traditional laboratory testing methods. Thus, treating physicians can administer appropriate therapies confidently. In turn, appropriate therapies reduce costs and shorten length of stay.

"In fact, for microbiology, the earliest fully-automated mass spec systems specifically designed for use in clinical laboratories are already in beta testing," Herold observed. "These are expected to earn FDA clearance over the next 6 to 18 months. As that happens, medical technologists will be using integrated mass spectrometry systems that are load-and-walk-away.

"In my view, these fully-automated mass spectrometry systems will trigger a fundamental change in microbiology, for example," he said. "Additionally, pioneering work provides evidence that mass spectrometry could have a similarly dramatic effect on immunoassays as well.

"Currently, mass spectrometry is assuming a larger role in clinical testing, even though this method is manually intensive," he noted. "What will accelerate acceptance by labs is the arrival of highly-automated mass spec systems into the clinical marketplace. Multiple vendors are poised to introduce such solutions.

Higher Accuracy

"More importantly, mass spec delivers results with higher accuracy, and at lower concentrations, than is possible with many immunoassays," stated Herold. "Use of stable isotope labeled internal standards, sample preparation, high performance liquid chromatography, and specific mass spectrometry methods lead to increased confidence that the right answer is obtained.

"We regularly see instances in which mass spec is the only instrument that will produce the correct answer needed for precise diagnosis," said Herold. "Testosterone is perhaps the poster child for mass spec testing. A growing number of endocrinologists view mass spec—rather than an immunoassay—as the most accurate method for measurement of testosterone in women and children.

"Physicians and lab medicine professionals seem to be moving in the direction of using mass spectrometry as the preferred method for all testosterone testing," he continued. "Of course, in this stage of its clinical acceptance as a diagnostic technology, there

are specific patient cases where mass spec is the best method for diagnosis. There are cases, however, where use of an immunoassay continues to be appropriate."

Factors Supporting Adoption

Herold took care to explain some of the strategic factors supporting greater adoption of mass spectrometry for clinical testing. "As with any change in healthcare, there are multiple reasons for this shift," he said. "At least four primary factors are driving this trend.

"First, the per-test cost for mass spec analysis tends to be less expensive (not including the initial capital investment for the instrument) when compared with other accepted methods," Herold stated. "At a time when lab test reimbursement and lab budgets are shrinking, this becomes an important consideration.

"Second, results are more accurate with enhanced sensitivity when the mass spec assays are performed properly," he continued. "Pathologists and laboratory scientists prefer such accuracy.

"Third, mass spectrometry can be faster—significantly so," Herold noted. "The faster time-to-answer is one way that labs can deliver more value to clinicians, since the rapid delivery of test results can contribute to improved patient outcomes and reduced costs for the healthcare encounter.

"Fourth, mass spectrometry can analyze multiple analytes simultaneously without sacrificing analytical precision or accuracy," he added. "This is another capability that is attractive to clinical labs.

"Take, for instance, the analysis of thyroid hormone levels" said Herold. "Using immunoassays, you would have to measure three thyroid hormones one at a time. However, with mass spec, it is possible to measure all three hormones simultaneously. The extension to steroid and pain clinic profiles are logical segues."

To date, the adoption curve for mass spec in clinical diagnostics has proceeded in a step-wise fashion. "Mass spectrometry was quickly adopted for drugs-of-abuse testing and for inborn errors of metabolism," he said. "Next, mass spec was adopted for use in testing for testosterone and vitamin D levels.

"These trends drove growth in the use of mass spec for clinical diagnostic purposes," Herold explained. "This was particularly true after it became apparent that mass spec was a viable way to perform a vitamin D test rapidly.

"It was widely known that, in recent years, some of the national labs set up their mass spec instruments to do vitamin D tests at the rate of one sample per minute for 24 hours a day six days a week," he recalled. "Typically on Sundays, these labs would perform maintenance on the instruments and then restart the machines again on Monday."

Mass Spec And Vitamin D

This happened at a time between 2007 and 2011 when the volume of Vitamin D specimens was literally doubling every six months. It was common to see some of these national labs charge patient fees of as much as $225 to run each vitamin D 25(OH) D test.

"The surging volumes of vitamin D specimens during this time gave lab scientists the idea that this testing could be done quickly with mass spectrometry and the volume would generate substantial revenue at a reduced cost per analysis," Herold observed. "Essentially, these labs were applying industrial pharmaceutical techniques to this area of medical laboratory testing.

"Here's a good example of the type of cost/benefit analysis a laboratory would do for vitamin D testing," he offered. "At our laboratory, we could perform the test here or send it out.

"To do the analysis in our lab, the cost of consumables for each vitamin D test via mass spectrometry would be $2.75 to $3," Herold said. "However, now in 2013, if we

Houston's Methodist Hospital Uses Mass Spec To Foster Lab and Pharmacy Collaboration

INNOVATIVE HEALTHCARE INSTITUTIONS are beginning to tap the capabilities of mass spectrometry in impressive ways. That was certainly the case when the results of a research study conducted by the departments of Pharmacy and Pathology and Genomic Medicine at the 1,000-bed **Methodist Hospital** in Houston, Texas, were reported.

The study showed that by using mass spectrometry, the pathology and pharmacy departments could collaborate to identify gram-negative bloodstream infections quickly and get patients started on appropriate antibiotics. This testing method allowed the patients to leave the hospital sooner than if conventional lab testing methods were used.

By reducing length of stay, the researchers were able to slash costs by almost $20,000 per patient. From this intervention, the total annual savings for the hospital could be about $18 million, the researchers reported.

Study Used MALDI-TOF

This study was published online in the *Archives of Pathology & Laboratory Medicine* on December 6, 2012. The article, "Integrating Rapid Pathogen Identification and Antimicrobial Stewardship Significantly Decreases Hospital Costs," explained that the researchers used matrix-assisted laser desorption ionization time-of-flight (MALDI-TOF) mass spectrometry to analyze microbial proteins in patients with blood stream infections (BSIs).

In clinical practice, use of MALDI-TOF technology for routine bacterial identification is in its infancy, the researchers reported. Therefore, their goal was to determine if mass spectrometry, in tandem with what they called antimicrobial stewardship, could substantially improve care for patients with BSIs compared with conventional testing.

Improved Patient Outcomes

"Early diagnosis of gram-negative BSIs, prompt identification of the infecting organism, and appropriate antibiotic therapy improved patient care outcomes and decreased health care expenditures," the study authors wrote. "In an era of increasing antimicrobial resistance, methods to acquire and rapidly translate critical results into timely therapies for gram-negative BSIs are needed."

By comparing outcomes for patients hospitalized before the intervention was implemented with the outcomes of those patients treated after implementation, the researchers reported decreased length of hospital stay (LOS) and lower costs.

After accounting for other factors that might affect LOS, they concluded that mean LOS in the preintervention group was 11.9 days versus 9.3 days in the intervention group. Mean hospital costs per patient were $45,709 in the preintervention group and $26,162 in the intervention group, representing a savings of $19,547 per patient, they reported.

"In our 1,000-bed quaternary care hospital, we project a cost savings of [about] $18 million annually with the implementation of this strategy for the management of gram-negative BSIs," the researchers reported.

sent it out, the best price we'd get from a national lab is about $20 per test on our high-volume account.

"To this amount, it is necessary to add the time and labor required to package the specimens and get the test results into the LIS," he stated. "If my lab can save $17 or more on each of 70,000 vitamin D tests every year, that reduces spending in my lab by almost $1.2 million.

"In turn, these savings would allow us to recover the cost of acquiring the mass spec equipment within the first four months of its use," Herold said.

"Once a lab has put mass spectrometry equipment into operation, it makes clinical and economic sense to add other tests," observed Herold. "That optimizes the return on the lab's capital investment.

More Productivity

"For example, today it is common to see a lab use mass spec to run vitamin D tests," he commented. "Then, that lab likely would add testosterone, drugs-of-abuse screens, and other tests. This makes sense because the more assays that are run on the mass spec, the greater the productivity attained from both lab personnel and instrumentation.

"There's another advantage that mass spectrometry equipment has over immunoassay analyzers," stated Herold. "Currently mass spec instruments tend to be more robust and hence have less down time for maintenance and repair than analyzers running immunoassays.

"Just a couple of years ago, that was not true," he recalled. "During that period, uptime for mass spec equipment was often problematic. But manufacturers recognized and addressed this failing.

Auto Samplers

"In my view, the only apparent weak point for the current generation of mass spectrometry equipment now is that the auto samplers are not designed to handle hundreds of thousands of tests per month. Equipment operated at that workload will experience some breakdowns.

"Another important distinction between mass spec and immunoassay analyzers is the accuracy of mass spectrometry. With immunoassays, it is necessary to contend with the potential for interference where a detection agent (such as an antibody) cross-reacts and binds with other similar immune-reactive species," he added. "This interference reduces the specificity of immunoassays, in general. Labs spend a lot of time addressing this problem.

"In contrast to immunoassay methods, mass spectrometry can identify the precise molecule in question," stated Herold. "Now, for mass spectrometry there is also less sample preparation than has been required historically—even for difficult analyses.

"Today's mass spec instrumentation supports running high-volume tests," he said. "It can also perform assays that may analyze different types of specimens, including serum, plasma, cerebrospinal fluid, and blood spot cards.

Increased Specificity

"Mass spec permits isolation of a specific molecular ion that can be further fragmented to create daughter ions, and which, as a whole, represent the mass fingerprint of the molecule," stated Herold. "This information can be used to specifically quantitate an analyte with high confidence. Compared with immunoassay this method increases the specificity of the analysis, which pathologists appreciate because it removes a level of uncertainty.

"Staffing to operate a mass spec testing program is another issue that labs must consider," he stated. "The good news is that each generation of mass spec analyzers is smaller and more user friendly. At the same time, these lab instruments are also becoming more sophisticated.

"The staffing requirements needed for a lab to run a mass spec depend on what the lab aims to do with mass spec and how fast it wants to introduce this equipment or expand what exists," said Herold. "The current state of mass spec instrumentation can be run by medical technologists who have been appropriately trained. As the next level of sophistication arrives for this equipment, a lab can continue running at the present level or it will be necessary to develop more sophisticated staff to use these instruments to their optimal limits.

"In fact, labs today would benefit from using lab staff willing to become more knowledgeable about mass spec as this

Mass Spectrometry Has a Long History, Now Gaining Acceptance for Clinical Testing

MASS SPECTROMETERS have been in use for over 100 years. The machines had their incarnation in the late 19th century.

Their first use for biological applications started in the mid-1950s. For most of their existence, however, they have been relegated to research applications as their characteristics made then incompatible with either unsophisticated users or high-throughput applications. New developments that make them more user-friendly and reliable are in the process of uncloaking a valued analytical tool that is now setting its sights on the clinical lab.

"Early on, mass spec equipment was both expensive and required operators with highly specialized training," said David A. Herold, M.D., Ph.D., Chief of Clinical Chemistry at the VA San Diego Healthcare System and a Professor in the Department of Pathology at the University of California, San Diego. "If it ran for more than a week without needing troubleshooting and maintenance you were lucky. It was the perfect recipe for an esoteric research device, not a clinical analyzer.

"But after mass spec vendors identified clinical analysis as an attractive opportunity for this technology, they have made it their mission to hone these machines into pillars of reliability and ease of use," continued Herold. "That process is ongoing, but without a doubt the technology has gained increased acceptance in the clinical lab over the past five to seven years.

"At least two advantages of mass spectrometry are the cost and precision of analysis," Herold noted. "Once you make the capital investment in a mass spectrometer, the cost per test is near equivalent or significantly less than comparable immunoassays. Consider as well the increased accuracy, precision, and sensitivity, and you've got a powerful combination that addresses both economic- and healthcare-conscious interests."

Herold also is the President and Scientific Chair of the **Association for Mass Spectrometry: Applications to the Clinical Lab** (*www.mascl.org*), which holds an annual conference covering topics that include the development and adoption of mass spectrometry for clinical analysis. The next conference will be March 1 to 5, 2014, in San Diego, California.

methodology and the associated technologies become more refined," advised Herold. "It would be ideal to get personnel involved who have an interest not only in mass spec, but in data analysis as well, since mass spectrometry testing generates large quantities of data, especially with the emergence of metabolomic and proteomic analyses.

"Meanwhile, labs are moving quickly to adopt mass spectrometry," noted Herold. "It is already in use at more than 600 hospitals in Europe. Academic and research hospitals here in the United States are actively using mass spectrometry as well.

"Currently, microbiology is leading the charge in getting mass spectrometry into the clinical lab," stated Herold. "Several manufacturers have applied to the FDA for clearance of their diagnostics.

"These are the reasons mass spectrometry has expanded quickly over the past few years," concluded Herold. "That it has gotten this far this fast is encouraging, and I believe it will continue to develop rapidly in the coming years." TDR

—Joseph Burns

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Lab Compliance Update

Tennessee AG Opinion Adds Unease to EHR Donation Issue

Based on state law, opinion is uncannily similar to an opinion issued in 2012 by the Washington State AG

ANOTHER STATE ATTORNEY GENERAL (AG) has issued an opinion on the donations of electronic health record (EHR) systems by clinical laboratories to referring physicians. The opinion says that such donations would violate Tennessee state law.

The Tennessee AG's opinion is similar to one issued in November in Washington State by its attorney general. Each of these state opinions is likely to cause confusion for labs because federal law allows donations by providers—including clinical laboratories—intended to help referring physicians acquire EHR systems.

On March 4, Tennessee Attorney General Robert E. Cooper, Jr., wrote that the Tennessee Medical Laboratory Act prohibits anyone from soliciting the referral of specimens to a medical laboratory or contracting to perform medical laboratory examinations of specimens in a way that "offers or implies an offer of rebates."

Violation Of State Law

"This provision would prohibit a licensed medical laboratory from making any monetary donation to a physician to cover the cost of software designed to manage the physician's electronic health records when the physician's office that receives the EHR donation either continues an existing referral arrangement with the donating laboratory or subsequently initiates an arrangement for referral of specimens to the donating laboratory for analysis," Cooper wrote.

The Tennessee opinion is similar to one issued on November 12, 2012, by the former Washington state Attorney General Rob McKenna. In his opinion, Cooper referenced that opinion, writing, "See also Washington Attorney General. Op. 7, 2012 WL 7148193…(Nov. 20, 2012) (reaching same conclusion in finding that Washington's anti-kickback provisions were not preempted by federal law)." The opinions by both state AGs also refer to "monetary donations" or "donating money."

Comments By Lab Attorney

Earlier, in response to the Washington AG's opinion, THE DARK REPORT interviewed attorney David W. Gee of **Garvey Schubert Barer** in Seattle. He stated, "It's hard to understand why the [Washington State] Attorney General would take the view that donating EHR software is illegal because that position directly undermines the federal government's statutory efforts to promote physicians' electronic health information connectivity. Likewise, the AG's opinion talks about a 'cash donation', but the EHR software donation permitted by the federal laws does not contemplate monetary donation to a physician." *(See TDR, March 4, 2013.)*

Both opinions are online. Tennessee's is located at: *http://tinyurl.com/d6atcxy*. Washington state's AG opinion is at: *http://tinyurl.com/cq9d7v5*. Lab administrators are advised to review their state laws on the subject of EHR donations to referring physicians. TDR

Lab Copays Announced By California Exchange

Some 2.6 million residents will be eligible to enroll in these state-subsidized health plans

CEO SUMMARY: California will operate one of the nation's largest health insurance benefit exchanges, as defined by the Affordable Care Act. Officials recently unveiled details about the exchange, to be called Covered California. Based on bronze, silver, gold, or platinum plan coverage, beneficiaries will be required to pay a copay of between $6 and $45 per medical lab visit. Open enrollment begins this fall and Covered California will commence operations on January 1, 2014.

CALIFORNIA IS THE FIRST STATE in the nation to establish the coverage parameters for its health insurance benefit exchange, due to become operational on January 1, 2014. At least one policy may prove troublesome for clinical laboratories.

As mandated by the Affordable Care Act of 2010 (ACA), California is taking the steps needed to launch its state exchange. Called **Covered California,** it will enroll consumers this fall at *www.CoveredCA.com.*

Covered California will be a big deal. According to Dana Howard, a spokesman for the exchange, it will insure 2.6 million state residents who currently are uninsured and are eligible for subsidized coverage under the exchange. For this year and next, California will use $684 billion in federal funding to get the exchange running and provide subsidies. Beginning January 1, 2015, the exchange plans to be self-sustaining. This means it will operate without federal support, Howard explained.

What is of interest to pathologists, clinical laboratory executives, and other providers are the details of how Covered California will provide coverage and how the participating insurers will reimburse providers.

In fact, one of the policies made public recently is that Covered California will require the beneficiary to pay between $6 and as much as $45 out of pocket for each laboratory visit, depending on the level of the beneficiary's coverage. This could create problems for clinical labs, since it may increase bad debt from patients and raise the cost to the lab to bill and collect these amounts.

Premium Costs Unknown

"Currently, we don't know the insurance premium costs [for Covered California] because 33 health insurance companies have submitted bids that we are evaluating now," Howard said. "Sometime in early summer we expect to select the insurers to participate in the exchange. We will then know the premiums and the dollar amount of financial assistance we will provide to consumers.

"In the meantime, we can show people what they will pay if they are eligible for a subsidy," continued Howard. "We know

how much an individual and a family will need to pay because it will be a percentage of their adjusted gross income as reported on their tax returns.

"For example, a family of four making less than $23,000 per year will pay $39 per month for family coverage under the standard benefit plans we are offering in the exchange," he explained. "Subsidies will be available to any eligible family that chooses the silver plan from our list of four plans, which range from bronze on the low end, to silver in the middle, and gold and platinum on the high end."

Households earning less than 250% of the federal poverty level can receive financial assistance by enrolling in a silver plan, per the details announced by Covered California. "The less income they earn, the more financial assistance they can receive. For example, individuals earning between 150% and 250% of the federal poverty level can expect to pay $20 to see a primary care physician, while those earning 100% to 150% percent would pay $4," said the Covered California statement.

Price Comparison Of Plans

"By offering a standard benefits plan, residents will be able to compare apples to apples when shopping for coverage," Howard added. California residents choosing the standard benefit plans would have an out of pocket maximum to pay each year that ranges from $2,250 to $5,200 in the subsidized silver plans to $5,000 for the gold plan, and $6,400 for the platinum. In these standard benefit plans, copayments for lab tests range from a low of $6 in the bronze and silver plans to $45 in the gold and platinum plans.

Clinical labs would be expected to collect the $6 to $45 copay for each lab test from those patients enrolled in these plans. If some residents required many expensive tests, the laboratory may need to collect much more—up to the out-of-pocket annual maximum specified by the beneficiary's plan.

The steady increase in health insurance premiums in California has been viewed as a serious problem. In a report in January, the **California Health Care Foundation** (CHCF) reported that the cost of health insurance premiums for California families rose 153% since 2002, more than five times the 29% increase in the rate of inflation.

Waiting For More Details

Those pathologists and lab executives in California who are following these developments can expect further details about lab test coverage guidelines to be announced in coming months.

For laboratory professionals in other states, the significance of Covered California is rooted in the fact that California is considered a bellwether state for political initiatives and cultural developments. For that reason, other states will closely study the design of Covered California as they take steps to develop their own state health insurance exchanges.

The Covered California exchange is one of 50 to be established in each state by January 1, 2015. Under the federal ACA, some states will run their own insurance exchanges, such as California and Massachusetts, which has operated the **Commonwealth Connector** exchange since 2006. Other states will let the federal government operate the exchanges for them.

Large Enrollment Expected

With an expected enrollment of 5.3 million residents, California's health benefit exchange will be one of the largest in the nation. For comparison, approximately 11 million people are currently enrolled in Medi-Cal, the state's Medicaid program.

Nationally, one goal of the Affordable Care Act is to provide health coverage to some 30 million Americans who currently lack health insurance. **TDR**

—Joseph Burns

Contact Dana Howard at 916-323-3632 or Dana.Howard@hbex.ca.gov.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last month, **Dignity Health** acknowledged that it is engaged in negotiations to sell its lab outreach business that is based in Stockton, California. The lab outreach program is known as **HealthCare Clinical Laboratories** and is associated with 294-bed **St. Joseph's Medical Center**. The story surfaced after Dignity Health (formerly know as **Catholic Healthcare West**) notified lab employees that the health system had put the laboratory outreach program up for sale.

MORE ON: Lab Sale

HealthCare Clinical Laboratories (HCL) is a substantial enterprise. In a news story published in 2009, it was reported that the lab handled 3 million specimens per year, earned gross revenue of about $80 million annually, and employed 365 workers. HCL acts as a reference laboratory for the Dignity Health hospitals, primarily those hospitals located in California.

CHINESE COMPANY INVESTS $22.4 MIL IN SALADAX

Now it is the turn of the Chinese to invest in American lab testing companies. On March 5, publicly-traded **Shanghai Fosun Pharmaceutical Co., Ltd.**, stated that it had invested $22.4 million in **Saladax Biomedical, Inc.**, of Bethlehem, Pennsylvania. Saladax develops and commercializes "novel diagnostic assays... for new and existing therapeutics." A division of Fosun in China will be Saladax's partner in that country and will be the exclusive manufacturer and distributor of Saladax's MyCare oncology dose management assays.

TRANSITIONS

- **Mission Health System** of Ashville, North Carolina, has appointed Priscilla Cherry as its Executive Director of Laboratory Services. Cherry has held executive positions with **Fairview Health System**, **Premier, Inc.**, and **Kaiser Permanente**.
- Haywood Cochrane Jr., was selected as Chairman of the Board for **DARA BioSciences, Inc.**, of Raleigh, North Carolina. He has served on its board since 2008. During his career, Cochrane was COO of **Roche Biomedical Laboratories**, CEO of **Allied Clinical Laboratories**, and CFO of **Laboratory Corporation of America**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 15, 2013.

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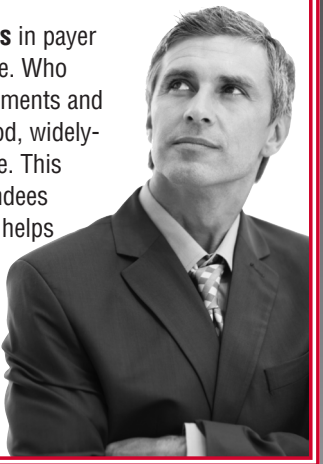
Preview–Jane Pine Wood, McDonald Hopkins, on…

Developments in Payer Contracting, How Labs Get Paid, Compliance and More

It's been an eventful year with plenty of changes in payer contracting, lab test reimbursement, and compliance. Who better to explain the consequences of these developments and provide useful insights than attorney Jane Pine Wood, widely-recognized for her acumen and hands-on experience. This session is a favorite of ***Executive War College*** attendees because it is chock-full of practical information that helps labs negotiate for more money while addressing changing compliance requirements.



For program details and to register, visit www.executivewarcollege.com

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- ***Cutting Your Lab's Cost of Send-out and Reference Tests: Powerful New Ways to Use RFPs to Reduce Spending.***
- ***New Consolidation Strategy for Hospital-based Physicians: Why Radiologists, Anesthesiologists, and Pathologists Are Forming Regional Supergroups.***
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