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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

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Theranos in the News, for Better and Worse

IT'S BEEN AN EVENTFUL COUPLE OF MONTHS for Theranos, the lab testing company that says its goal is to disrupt the clinical laboratory industry. Novelists cannot write fiction as compelling as the unfolding real story about this controversial company.

During March and April, *The Wall Street Journal* published a series of articles that revealed the extent of the problems Theranos had with CLIA inspections of its clinical laboratory in Newark, California. The Journal published its analysis of the CLIA inspection report and the serious deficiencies identified during lab inspections that happened last fall and earlier this year.

On April 13, the Journal published the sanction letter that the federal **Centers for Medicare and Medicaid Services** had sent to Theranos on March 18. CMS wrote that, "Based on a finding of immediate jeopardy and the laboratory's failure to meet all CLIA condition level requirements," it proposed sanctions against Theranos.

The sanctions include revocation of the lab's CLIA certificate and cancellation of the laboratory's approval to receive Medicare payments. With revocation of the lab's CLIA license, the lab's owners and medical director will be banned from "owning, operating (or directing) a laboratory for at least two years from date of the revocation."

The next hammerblow to Theranos came just five days later. On April 18, the Journal published a story describing how Theranos was the subject of a criminal investigation by the **U.S. Department of Justice** and that the S**ecurities and Exchange Commission** was looking into the activities of the lab company. Theranos acknowledged that it was aware of these federal probes.

For its part, Theranos made two significant announcements last month. On April 7, it disclosed that it had named six more members to its two-member Scientific and Medical Advisory Board. Five of the six new members are past presidents of the **American Association of Clinical Chemistry** (AACC).

Next, on April 18, the AACC issued a press release stating that Theranos Founder and CEO Elizabeth Holmes would present scientific data on its diagnostic technology at a plenary session of the AACC's annual meeting in Philadelphia. The session will happen at 12-1:30 PM on Monday, August 1. That may turn out to be the best-attended session at this year's annual meeting! TDR

At Exec War College 2016, Two Big Lab Market Trends

Consensus among this year's expert speakers is that opportunities abound for innovative labs

CEO SUMMARY: What happens when 100 lab experts interact with an audience of more than 850 lab administrators, pathologists, and IVD executives from across the United States and seven other nations? A consensus of sorts emerges and during this 2016 edition of the Executive War College on Lab and Pathology Management, that consensus was how: 1) the pace of change in healthcare is unprecedented... and increasing; and, 2) genetic knowledge is poised to swiftly transform medicine.

TWO IMPORTANT LAB MARKET INSIGHTS EMERGED from the more than 60 sessions and 100 speakers at this year's *Executive War College on Lab and Pathology Management.*

The first market insight involves the ongoing revolution in how healthcare is organized, how clinical care is delivered, and how providers are reimbursed. Not only is the current rate of change happening at an unpredecented pace, but there was consensus among the experts that lab executives and pathologists should expect changes to come even faster during the next 24 to 48 months.

The second market insight centers upon the expert consensus that both the profession of laboratory medicine and the house of medicine are poised for a revolution in clinical care. This will come as a direct result of the tsunami of knowledge that is emerging from research into human genetics, proteomics, microbiomics and other related "omics."

These conclusions are credible. They reflect not just the opinions of the 100 speakers at this year's program, but also the reactions to these presentations by the more than 850 lab executives, pathologists, IVD managers, and IT vendors in attendance at this year's meeting in New Orleans on April 26-27.

Clinical labs and anatomic pathology groups would be well served to review their existing clinical, business, and financial strategies informed by these two market insights. It is timely to assess how a faster pace of change will influence the transformation of healthcare and of lab testing services. A swifter rate of change

has the potential to significantly influence the effectiveness of the lab's current clinical and finanical strategies.

That influence can be both negative and positive. A lab that doesn't respond to changes in clinical practices will be vulnerable. On the other hand, a lab can benefit from those same changes if it tracks this clinical transformation and introduces new diagnostic testing services that help physicians achieve better patient outcomes.

Multiple examples of significant transformation of hospitals and health systems were visible at this year's *Executive War College*. For example, in Arizona, **Banner Health**, the state's biggest health system, based in Phoenix, recently acquired the two-hospital **University of Arizona Health Network** in Tucson. It is now integrating those hospitals so they have the same EHR and IT systems.

Achieving Lab Integration

These developments were described in a keynote presentation by David A. Dexter, President and CEO of **Sonora Quest Laboratories**, a joint venture owned by Banner Health and **Quest Diagnostics Incorporated**. His laboratory has been working to fully integrate the laboratories of the University of Arizona Health Network with those of Sonora Quest and **Laboratory Services of Arizona**, the Banner inpatient lab organization.

Another development in Arizona is the growth of accountable care organizations (ACOs). Banner Health participates in multiple ACOs and has been successful with Medicare's Pioneer ACO program. Dexter discussed how Sonora Quest Laboratories is changing in the ways needed to support physicians delivering care to ACO patients.

Dexter emphasized that it is important for all lab organizations to understand the Triple Aim of the **Centers for Medicare & Medicaid Services** in order to succeed during the ongoing transformation of healthcare. He then explained that, "at CMS, the Triple Aim focuses on the following:

1) "Improve population and community health;
2) "Seamless coordination of care; and,
3) "Reduce per capita costs through improvement.

Medicare's Triple Aim

"Sonora Quest Laboratories is working to support the Triple Aim," he continued. "ACOs need data analytics in real time that is delivered to care coordinators to make it actionable. This data also needs to support providers' key metrics for CMS.

"The ACO data load into the population health software is typically four to 12 weeks behind real time," he continued. "That creates an opportunity for Sonora Quest Laboratories to provide its data in real time to both the ACOs and the clinicians treating the ACO patients. We are investing significantly in information technology so as to provide such data in real time."

On the East Coast, the laboratory division of **Northwell Health** (formerly **North Shore-Long Island Jewish Health**), is dealing with most of the same changes happening to healthcare in Arizona. As the nation's largest urban health system, Northwell Health operates 21 hospitals and more than 450 practice locations.

Lab Services At Northwell

In his keynote presentation, James M. Crawford, MD, PhD, Executive Director and Senior Vice President for Laboratory Services at Northwell Health, shared his lab's strategies to add value that contributes to improved patient outcomes while helping reduce the cost-per-encounter.

Similar to the laboratory integration happening in Arizona as hospitals and health systems merge into ever-bigger organizations, in the New York metro, Northwell's lab division has formed a laboratory joint venture. "The **CLNY Alliance Network** now includes, not only

Large-scale, Whole-Human Genome Sequencing Underway in UK and at Human Longevity, Inc.

ONE SPECIAL HAPPENING at this year's *Executive War College* was the back-to-back keynote presentations by leaders of two organizations that have already sequenced the largest number of whole-human genomes in the world.

Human Longevity Inc., of San Diego, was first to present. This presentation was followed by the **100,000 Genomes Project** of the United Kingdom. HLI has already sequenced 25,000 whole human genomes. The 100,000 Genomes Project has sequenced about 8,000 whole human genomes.

Human Longevity, Inc., is a company established by J. Craig Venter, PhD, Peter Diamondis, and Robert (Bob) Hariri, MD, PhD. The company's goal is to assemble the "world's largest and most comprehensive database of whole genome, phenotype and clinical data." It will use this data to "extend and enhance the healthy, high-performance lifespan and change the face of aging." It will do this by solving "the diseases of aging" and by "changing the way medicine is practiced."

In contrast, the 100,000 Genomes Project was organized by the **National Health Service** (NHS) of the United Kingdom. Its focus is on cancer and rare diseases and the goal is to use the knowledge gained from a study of the genome data base to create useful clinical care pathways that benefit UK patients.

Metabolome & Microbiome

"It is important to understand that HLI is working to combine information from the human genome with that of the metabolome and microbiome," stated Brad Perkins, MD, Chief Medical Officer at HLI. "One primary tool we are using is machine learning in order to make sense of the huge amounts of data that are being generated."

Perkins surprised the audience by describing the role of imaging, including MRI and DXA, as part of the data collected on individuals. "Among other things, we use this data to create an avatar of the individual. The avatar is then used by the individual to look at the different aspects of his or her health.

"Currently, our comprehensive service is priced at $25,000," said Perkins. "For each individual, we are identifying a growing range of findings that are significant and/or actionable."

100,000 Genomes Project

In the following keynote presentation, Sue Hill, OBE, PhD, Chief Scientific Officer for the National Health Service England, described how this program is establishing a national infrastructure to collect specimens, perform the sequencing, then store and analyze the data.

"The types of specimens collected for gene sequencing include formalin-fixed tissue, fresh frozen tissue, and blood," stated Hill. "Typically these specimens come from patients with cancer or a rare disease, and their family members.

"In this current phase, researchers are focusing on these cancers: breast, prostate, colorectal, ovarian, lung, and CLL," she continued. "Study is commencing on renal cancers and sarcomas.

"To make genetic medicine a reality, over the next 10 years the 100,000 Genomes Project will be fostering the development of resources such as a genomic laboratory infrastructure and centers of excellence while informing new pathways and models of care," stated Hill. "A major goal is to apply whole-genome sequencing routinely in cancer and in other clinical conditions in support of a functional genomic pathway that is fully deployed, both in real-time care and also for monitoring."

Taken collectively, the presentations of Perkins and Hill gave the audience a behind-the-scenes look at the rapid progress being made in whole-human gene sequencing and the interpretation of that data.

the lab testing sites of Northwell, but also another four core laboratories and 12 hospital labs of the other JV partners," noted Crawford. "The goal of this laboratory joint venture is to compete for outreach business while returning clinical and financial benefits to the JV partners.

Regional Lab Network In NY

"For example, combined, the labs in the CLNY Alliance Network produce 34 million billable tests per year and have an operating budget in excess of half a billion dollars!" he exclaimed. "Through standardization and some consolidation, the JV is on track to deliver $40 million in savings to the partners in the next 30 months. It is also positioned to expand its market share of office-based physicians in the region."

In fact, the Northwell Health lab division is at the front of the curve in using collaborations to advance its clinical mission in ways that also deliver substantial financial benefits. "Like all health system labs, we recognize the need to be at the cutting edge in molecular diagnostics and genetic testing to support population health management and personalized medicine," noted Crawford.

"That raises a critical question: where does the lab get the capital needed to acquire state-of-the-art gene sequencing instruments?" he asked. "It is the classic 'make or buy' decision that confronts every lab that wants to offer a new test.

Partner For Genetic Testing

"Our decision was to partner with an organization that is already at the front edge of genetic testing and was willing to collaborate with us in ways that fully support our clinical mission to our parent health system," noted Crawford. "We then spent almost three full years visiting potential partners, developing a request for qualifications (ROQ); then doing site visits of the respondents to the ROQ.

"Late last year, we wrapped up negotiations with our choice of a business partner," he continued. "In January, we launched a shared genetic testing partnership with **Bio-Reference Laboratories, Inc.**, of Elmwood Park, New Jersey.

"This is a limited liability corporation (LLC)," noted Crawford. "The master agreement for what we describe as a strategic alliance addresses several important issues. There is a Laboratory Service Agreement (LSA) that governs laboratory testing. It covers genetic counseling with test selection, test interpretation, and standard reporting requirements.

"For enhanced genomics, Northwell signs out the reports," he added. "Other elements address genomic tumor boards, strategic teaching, the generation of data, who owns that data, and how market value will be defined."

Precision Health

Crawford next discussed how the Northwell lab division is positioning itself to contribute to the further integration of clinical care. "Population health management and precision medicine both require labs to master information technology in sophisticated ways," observed Crawford. "When lab data is combined with other types of clinical data, it becomes possible for pathologists, PhDs, and the lab team to collaborate with physicians in innovative and productive ways that directly benefit patients.

"One of our early successes with the use of enriched lab test data was in acute kidney injury (AKI), which is under-recognized and under-diagnosed," he observed. "In a pilot program with one Northwell hospital, we instituted a 'delta creatinine' alert pilot program. Better use of this low-cost lab test helped to achieve earlier diagnosis of more cases of AKI.

"Not only did patient outcomes improve, but more accurate diagnosis and coding for AKI generated additional revenue of $2.7 million to Northwell in 2015," said Crawford. "The AKI program is now being implemented systemwide." TDR

200-Analyte Med Panel Adds Value for Physicians

Lab designs mass spectrometry assays to help doctors, hospitals deliver value-based healthcare

CEO SUMMARY: Delivering more value with lab tests requires going beyond simply working with physicians to improve test utilization by focusing on unnecessary or inappropriate tests. PeaceHealth Laboratories in Oregon successfully executed a two-step strategy to add value with its testing services. First, the lab combined a proprietary test with a new care protocol to improve patient care. Second, the lab staff went outside the lab to engage clinicians to develop new methods to improve patient outcomes.

BY CREATING AN UNUSUAL PROPRIETARY MULTI-ANALYTE LAB TEST, an Oregon laboratory delivered much greater value to office-based physicians, including a reduction in emergency room visits and improved patient compliance with physicians' orders.

The lab's two primary goals with this project were to help physicians: a) achieve better outcomes when treating inpatients and ambulatory patients with common chronic conditions; and, b) manage patients on pain medications or abusing drugs. Another goal was to help reduce emergency room visits.

Pathologists at **PeaceHealth Laboratories** in Springfield, Oregon, developed a test called PtProtect, a comprehensive urine drug test panel that detects more than 38 medications and other substances in a patient. They also developed a patient-management protocol for physician office staff to follow when treating chronic pain patients.

After successfully testing how the PtProtect UDT and the patient-management protocol worked in a physician clinic, the pathologists developed a second panel of tests to detect more than 200 common medications in patients' plasma and urine. This test is called RxAdhere Medication Safety Panel.

"The RxAdhere test runs on a mass spectrometry analyzer and thus can produce the molecular signature of common medications present in a patient's blood," stated Ran Whitehead, the lab's CEO and Chief Mission Officer.

"We don't know of any other laboratory in the country that has developed a diagnostic panel that uses mass spec to detect more than 200 common medications used for treating common chronic conditions," he commented.

Small Study, Big Results

Before the RxAdhere Medication Safety Panel went into development, the pathologists ran a proof-of-concept test for the PtProtect assay and patient-management protocol in a 16-physician primary care clinic with two locations.

The study was small, Whitehead acknowledged, but successful given that it

drove down ER visits and increased compliance among patients participating in the protocol.

These two metrics are important to physician groups and health systems as they make the transition away from fee-for-service care and are reimbursed for value-based care.

Market Roll-Out Of Test

Now that PHL has had success with the PtProtect protocol, the laboratory sales staff has introduced the RxAdhere test panel and the PtProtect protocol to other physician groups and hospitals in the three states PHL serves: Alaska, Oregon, and Washington.

"In this case study of the lab test and the PtProtect pain medication protocol, there was a 37% decrease in ER visits among patients who had been on long-term prescriptions for pain medications," explained Whitehead. "There was also a decrease of 11% in our patient discrepancy rates.

"We record discrepancy rates as being the difference between what medications a physician believes the patient is taking and what's actually onboard in the patient's system," he said. "That decrease in discrepancy rates means patients involved in this study had an increase in patient compliance with the prescription regimens those patients got from their physicians.

More Efficient Patient Visits

"We also recorded that these patients had more efficient visits with their physicians and the physicians' staff," he added. "This is important because office visits with chronic pain patients often take up more time than visits with most other patients. That causes stress in a busy physicians' office, since staff members are tied up with patients beyond the normal time. Therefore, it is significant that our study recorded a decrease in staff stress as well.

"Now, the good news is our lab has this test and we know it works because it was evaluated in a clinic setting," stated Whitehead. "That means we have data that can be used in discussions with providers as we introduce our assay and protocol to other physician clinics. But, as with anything in healthcare, adoption rates can be painfully slow.

"That is why the study we did with the 16-physician clinic is useful," he added. "It required our lab team to work closely with physicians and other staff to develop a multi-step protocol that would identify patients who would be best suited to have this test, then guide the clinic staff on how to work with those patients over time.

"The program also involved getting certain patients to agree to medication agreements and then assessing the test results from those patients who were being treated under the PtProtect protocol," noted Whitehead. "Staff following this protocol met with those patients to ensure that they continue to comply with their medication agreements.

Adding Valued Services

"Under the PtProtect protocol, staff do a risk assessment of those patients identified by physicians as being appropriate to participate in the program," Whitehead explained. High-risk patients would be tested once every three months and low-risk patients would be tested every six months.

Building on its success with the development and implementation of its proprietary PtProtect test and protocol for managing patients taking pain medications or patients abusing drugs, PHL now is evaluating its RxAdhere Medication Safety Panel and the protocol that guides physicians using this test.

"As with PtProtect, RxAdhere is designed to facilitate detection of medication adherence and adverse drug events (ADEs) for medications used when treating patients with common chronic conditions," explained Whitehead.

"Currently we are working with community pharmacists and the medical exec-

utive committees in the various hospitals that we serve to determine how RxAdhere tests will be integrated into the inpatient and ambulatory continuum of care," he commented. "At $250, the test is reasonably priced, but it's not inexpensive either. Cost is one reason why a provider does not want to test everyone who walks in through the door.

Solving Similar Problems

"Both our PtProtect and RxAdhere programs solve similar problems that physicians and health systems have in treating patients," stated Whitehead. "We think these added-value lab services will be well received.

"Currently we are working to develop RxAdhere protocols that are appropriate for use in hospital settings," he observed. "That would include having order sets programmed into the electronic medical record system in hospitals.

"Use of RxAdhere test panel can reduce inpatient ADE's, reduce extended hospital stays and expense through identifying common medications that are not in the medical record (such as antiepileptic, anticoagulants, antiplatelets, antihypertensives, antidepressants and antipsychotics) and through identifying non-adherence to outpatient medications," Whitehead explained.

"Accurately identifying these outpatient medications at admission will improve medication reconciliation and help maintain patients on critical medications. It provides an accurate list of outpatient medications on discharge to help avoid ADEs in the ambulatory setting," he added.

Study Of 300 ER Patients

"Part of the RxAdhere validation included testing more than 300 patients at ED arrival to compare outpatient medications detected by RxAdhere with the patient's medication reconciliation record," he said. "The data showed that 41% of these ER patients were non-adherent for at least one prescribed medication and 31% of outpatients used at least one medication not in their medical record.

"We also believe that use of the RxAdhere test could be useful on the outpatient side for improving outcomes for common chronic conditions by improving medication treatment decisions (such

Peace Health Lab Working On Next Value-Add Service

BUILDING ON ITS SUCCESS WITH THE CREATION and implementation of its proprietary PtProtect test and protocol for managing patients taking pain medications or abusing drugs, Peace Health Laboratories is working to add more value with its pain management service.

It has developed a 200-analyte assay called the RxAdhere Medical Safety Panel. "RxAdhere is an expansion of our pain management program," observed PHL President Ran Whitehead. "With RxAdhere, we will scan not only for narcotics and drugs of abuse, but for other medications that patients take for a wide variety of ailments.

"RxAdhere is designed to make it easy, fast, and accurate for physicians, hospitals, and health systems to do medication reconciliation among ambulatory patients and hospital inpatients," commented Whitehead. "As with PtProtect, RxAdhere is designed to record discrepancy rates for all medications that a patient takes regularly.

"We believe RxAdhere will be useful because different doctors often prescribe different medications to patients," said Whitehead. "But how would a physician determine which medications have been prescribed to his patient by other providers and which of those medications the patient is actually taking?

"If a patient takes medications that can cause an adverse drug event (ADE), physicians need to know that," he said, adding, "Avoiding patient harm and unnecessary hospital readmissions is critical."

as by changing dosage or medications), and by reducing hospital admissions (for patients with congestive heart failure, as an example)," added Whitehead.

"One challenge to introducing a new lab assay and care protocol such as the PtProtect Pain Medication Monitoring Program is that any cost of more than a couple hundred bucks gets physicians nervous about widespread use," said Whitehead. "Also, physicians here in the Pacific Northwest seem to be very conservative when it comes to the patient's pocketbook.

"Therefore, our lab is working to introduce RxAdhere and the associated clinical care protocol in the right way with the right population and then demonstrate its value," he emphasized. "Our expectation—backed by the first study—is that use of the RxAdhere test and the protocol will help hospitals and health system avoid significant downstream costs. This will change how they monitor patients with common chronic conditions and patients will be healthier and need less acute care.

Preventing Readmissions

"For example, if a hospital can prevent a readmission or ADE, that could be several thousand dollars of cost avoidance," observed Whitehead. "As a result of an intervention that utilizes this lab test and protocol, we hope to begin documenting a number of avoided readmissions as a result of this intervention.

"We have already documented a reduction in inappropriate emergency department visits from patients using narcotics," he added. "ED visits are expensive and health plans don't always reimburse adequately for them.

"What's more, ED staff use up a lot of time that could be dedicated to other patients," continued Whitehead. "Early evidence shows patient outcomes are better and the savings can be substantial when the PtProtect test is used appropriately. Similar results should occur with the RxAdhere Medication Safety Panel."

Pathologists and lab executives looking for ways to add value to their lab testing services should take note of the fact that the lab team at PHL identified clinical opportunities where the right lab test—combined with an appropriate care protocol—could document improvements in patient outcomes while also delivering cost reductions that were substantial.

Essentially, the team at Peace Health Laboratories looked outside their lab for this opportunity to add value with lab tests, then engaged referring physicians in ways that were a win-win for the patient, the physician, the health system, and the health insurer. TDR

—Joseph Burns

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University of Colorado Lab Has Multi-Analyte Drug Test

SINCE 2014, A COLORADO LAB has offered hospitals and physicians a test capable of detecting 112 compounds and more than 500 illicit and brand-name drugs.

CU Toxicology is a nonprofit lab that is part of a public-private partnership with the **University of Colorado School of Medicine's** Department of Anesthesiology. Jeffrey Galinkin, MD, Chief Medical Officer of CU Toxicology, developed the test, which utilizes mass spectrometry. *(See TDR, February 24, 2014.)*

Kaiser Permanente Colorado in Denver uses this assay. "Using CU Toxicology's multiplexed mass spec method, which is confirmatory testing, thus gives our ordering physicians a one-month drug history window, rather than only a week's look, which is uniquely important with respect to managing these patients," stated Michael Sheehan, PhD, the Technical Operations Manager for Kaiser's central laboratory in Denver, in an interview with THE DARK REPORT.

Lab Goes 'Cold Turkey,' Stops Billing Health Plans

Tired of uncertain payment, Kailos Genetics slashes prices, goes direct to patients and docs

CEO SUMMARY: Last year, Kailos Genetics stopped collecting third-party payment, dropped its prices sharply, and started marketing its genetic-screening tests directly to consumers and physicians. At the time, 100% of its revenue came from third-party payers. Today, it gets 100% of its revenue from consumers. After eliminating third-party payment, revenue dropped precipitously, but is now rising again. Can this model work for genetic and molecular testing labs struggling with uncertain insurance reimbursement?

FOLLOWING MONTHS OF FRUSTRATING efforts to get health insurers to reimburse for their genetic tests consistently, executives at **Kailos Genetics** decided to go "cold turkey." They stopped sending claims to payers and asked patients to pay directly for these tests.

This business strategy reflected the reality of today's managed care marketplace. It is tough for new genetic testing companies to get payers to reimburse for these lab tests.

It was six years ago when a group of entrepreneurs from the **Hudson Alpha Institute** formed Kailos Genetics. Their goal was to provide cutting-edge genetic testing to consumers. Following the advice of consultants and other labs, Kailos built its business on getting reimbursement from Medicare and commercial health insurers.

But what Kailos learned will not surprise any clinical laboratory seeking reimbursement for genetic testing. "The insurance payment model left physicians and their patients frustrated and angry," stated Chief Scientific Officer Troy Moore. "The billing staff at Kailos was unhappy as well."

So on June 1, 2015, Kailos stopped seeking third-party payment. It dropped its gene test prices sharply, and went direct to consumers.

At the time, Kailos was getting 100% of its revenue from third-party payers. Today, it gets 100% of its revenue from consumers. After adopting the strategy to work directly with consumers and eliminate third-party payment, revenue dropped precipitously over the first few months. It has recently begun to inch back up again as Kailos approaches its one-year anniversary selling genetic tests direct to consumers (DTC), Moore said.

Getting No Satisfaction

"I have never been part of a business where everyone was unhappy," he commented. "When we started Kailos, our goal was to offer a service that customers wanted, meaning it would satisfy our customers so they would come back to us.

"If physicians and patients are happy with us, then maybe later in their lives,

they will come back to us for more gene testing," he added. "But there was little satisfaction with the third-party reimbursement model. The whole payment side of the healthcare business is upside down."

Fighting To Get Paid

From the day it was founded in 2010, Kailos operated under the typical lab-test reimbursement model. "But it was extremely frustrating," noted Moore. "As most genetic testing companies discover: Your claims either don't get paid or you get paid less than you expected. Either way, your lab must fight for every bit of it. That is why—at the start of last year—we decided: that's not how we want to do business."

Last year, from January through May, the 20 employees at Kailos in Huntsville, Alabama, prepared to shift from insurance reimbursement to only billing patients for payment. Moore did not want to do both. "It's too risky," he observed. "If you make one mistake, your lab could be open to a charge of fraud.

"We got into this business to introduce advances in genetic testing to physicians and patients and not to fight with insurance companies," he added.

"To make this change in our billing policies, we had to shift from receiving regular test orders from physician groups to the need to educate patients about our lab test offerings," explained Moore. "This was a considerable challenge. We found that, when we are successful in getting in front of patients, they definitely respond.

Patients Respond To Prices

"So, while revenue did drop precipitously during the changeover," he commented, "today we see an exciting growth trend in front of us as each month as more patients take control of their own genetic healthcare information.

"Originally we wanted to do this with whole genome sequencing but we eventually realized it would not be feasible or profitable," said Moore. "Next, we thought that, by using gene sequencing and our proprietary enrichment technologies, we could drive down costs and we could pass those savings along to customers. But that didn't work because getting our claims paid by health plans was unpredictable, took too much time, and caused a lot of aggravation for everyone, including patients and their physicians."

At the time, Kailos priced its tests at around $1,500, a level similar to what other genetic testing companies were asking. "We got advice from many people about how to price our genetic tests and at what amount.

"Consultants told us our lab company would get much less than what is billed," recalled Moore. "Yes, we learned to expect less and we also learned that it is necessary to give Medicare the best price."

Strategy For Pricing Tests

Ironically, Kailos would have set a lower price if it had any confidence that it would be paid in full. "If healthcare was like a normal business, there'd be no reason to charge $1,500," declared Moore. "But healthcare is not a normal business.

"Even if our lab submitted a claim with all the proper information, we never knew what we'd get paid by that insurer," he continued. "Some test claims got paid, some got paid less, and some got rejected."

Moore pointed out that the problem with rejected claims is that a laboratory cannot then offer the patient a lower price for that same test. "Anytime an insurer rejected a claim, the patients were responsible to pay the whole amount because of health plan requirements—not to mention the need to comply with anti-kickback laws," he said. "Plus, labs need to give Medicare the best price, and labs must follow the contracts they have with health insurers. Thus, patients had to pay the full amount.

"The full amount then became a surprise medical bill to the patient," added Moore. "No one wants this. This is particularly true for patients who may not always understand how health insurance works—or doesn't work, in many cases.

A Surprise No One Wants

"If a patient's insurer paid the bill, we never heard from the patient," observed Moore. "But if the insurer did not pay the lab test claim, our lab had an angry customer. And there's no way to make a customer happy if he/she gets stuck with a $1,500 bill for a genetic test that their physician assumed the health insurance would cover.

"For all these reasons, Kailos decided it is best to have patients pay directly," he stated. "That meant establishing prices at consumer-acceptable levels. Today, we have a fair price structure and our lab does not pay a team of people to call insurance companies trying to get payment for our claims.

"We did consider lowering prices and continuing with insurance reimbursement, but we are a small organization with limited resources," noted Moore. "Ultimately, we did not think our change would shift the discussion with payers in a timeframe that would be meaningful for our lab company and our patients.

Patient, Physician Education

"We still deal with each patient's physician and that's complicated but we manage it all internally," explained Moore. "The goal is to make it easy for the patient to order a test because we consult with the doctor on the back end. Primarily we market to patients and to nonprofit organizations that reach out to patients about the value of genetic testing."

About half of Kailos' business comes directly from patients ordering genetic tests online. The remaining half comes from other labs referring patients to Kailos as a reference laboratory.

By Selling to Consumers, Kailos Can Discount Tests

THERE IS A BIG ADVANTAGE TO ESTABLISHING a fee schedule for genetic tests that is priced at levels that are friendly for patients and consumers, such as was done by Kailos Genetics last year. This was when the lab company decided to cease submitting claims to health insurers for its tests.

That advantage of selling directly to patients and consumers is that the lab can run sales on its menu of genetic tests and consumers will recognize the value offered by the lower sale prices. Last month, Kailos offered a sale on all but one of its genetic screening tests. That one test, a cancer screening assay, costs a patient $225.

The usual price for most of the tests offered by Kailos is $299. One example is PGX Complete, which identifies how a patient would respond to 80 different medications. In the April sales offer, however, PGX was half off.

"If a patient is interested in how he or she will respond to specific classes of medications, such as antidepressants, then he/she would choose a more-targeted test and those are priced lower," explained Troy Moore, Chief Science Officer. "Through the end of April, we set prices lower than usual. Those prices will roll back up to $299 and $149 in May."

Here's the test list and prices from the Kailos web site on April 22:

- ADHD: $149 (normally $299)
- Antidepressants: $99 (normally $299)
- Pain management: $99 (normally $299)
- Plavix: $99 (normally $299)
- PGX complete: $149 (normally $299)
- Tamoxifen: $99 (normally $299)
- Cancer screening: $225
- Oral contraceptives: $99 (normally $149)
- Stomach acid reducers: $99 (normally $149)

"When patients visit our website, they pick the test they want, pay for it, and tell us who their physician is," he said. "From there, we reach out to the physicians and let them know that their patient has ordered testing with us. We explain who we are and that the doctor will get a copy of the test result, as will their patient.

"Typically, for our cancer screening test, the physician gets the test result two days before the patient does," continued Moore. "Also, the physician has access to our genetic counselors or our medical director if they have any questions. Many times, genetic testing is new for physicians. So we educate them and explain how our testing works and how to understand the results of the genetic tests.

Consumer Model Doing Well

"After almost a year, I'd say the consumer model is doing well," he noted. "This is why we started Kailos in the first place: to bring these techniques and technologies, especially next-generation gene sequencing, to patients and to physicians in clinics."

Although revenue dropped, layoffs were unnecessary. "Instead of having a lot of people on our staff calling insurance companies, we have the same number of employees. Much more of their focus is on customer support now," he said.

"With insurance reimbursement, your customer is the patient but you never get to talk to that customer. Instead, at best, you talk to the physician. But under this new model, we get to talk to patients about what they want. And we can provide them with the information they need through educational videos, counseling, and strong customer service," he concluded.

In one important way, Kailos has returned to its original mission: meeting patients' needs, something it could not do well when its income depended on third-party payments. **TDR**

—Joseph Burns

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Counsyl's Strategy Is to Be Friendly to Patients, Payers

ONE MAJOR HEALTHCARE TREND that tends to be overlooked by many clinical lab executives and pathologists is the growth of the number of people insured by high-deductible health plans. There are now tens of millions of people with HDHPs.

Health Affairs Magazine notes that, "in 2015, 24% of all workers were enrolled in a HDHP with a savings option. This is a dramatic rise since 2009, when just 8% were covered under such plans. The latest survey also suggests that 46% of employees have annual deductibles of over $1,000."

These statistics relate to individuals with health benefits obtained through their company. To this number must be added the approximately 10 million people who buy health insurance through the Affordable Care Act exchanges. Annual deductibles for these policies range from $5,000 for an individual to $10,000 for a family.

One company that recognizes the opportunity to better serve patients while also meeting the needs of health insurers is **Counsyl, Inc.**, of South San Francisco, California. Last year, THE DARK REPORT profiled its unique lab test pricing tool. This tool allows patients to determine the out-of-pocket cost of their laboratory test before the physician places the lab test order. *(See TDR, August 3, 2015.)*

Counsyl reported that 50% of its lab test volume is run through this tool. Best of all, it has enjoyed a 63% increase in patient payments while seeing a rise in patient satisfaction scores to 4.9 of a possible 5.0.

Health insurers seem to like Counsyl and its gene test menu. Counsyl executives told THE DARK REPORT last year that its tests were priced at 50% to 90% less than competing labs. At the same time, Counsyl said that it "holds managed care contracts that allow it to be an in-network benefit for approximately 80% of all the commercial lives in the United States."

Compliance Update

Attorney Cautions Clinical Labs Against Waiving Patient Fees

Mix of federal and state laws, plus payer policies, creates heightened risk from misinterpretation

WHEN A CLINICAL LAB WAIVES patients' fees in exchange for lab test referrals, competing labs face a legal dilemma.

If the competing lab does not match the offer, it could lose volume to this aggressive sales technique. But if the lab does match the offer, it could run afoul of health plan requirements not to waive fees and it could face investigations from federal and state regulatory agencies for offering an inducement to the referring physician or to the patient.

Peril For Regional Labs

"The situation is most pressing for small and regional labs when a large national lab offers to waive patients' fees because the smaller labs find it difficult to compete by doing that testing for free," stated Jeffrey J. Sherrin, a health law attorney with **O'Connell & Aronowitz PC** in Albany, N.Y., who has extensive experience representing clinical laboratories.

Public lab companies have been the most prolific users of this scheme, known as "waiver of charges for managed care patients." It is based on an OIG Fraud Alert issued in December 1994. *(See TDR, August 26, 2002.)*

One recent example of its use surfaced in Florida. A physician there was given a letter signed by a representative of **Quest Diagnostics Incorporated**. In the letter, Quest Diagnostics stated it would not submit lab test charges to "**UnitedHealthcare** Fully-Insured Products, Golden Rule, The Empire Plan, United Medical Resources and Oxford." **Laboratory Corporation of America** has an exclusive national lab contract with UnitedHealth. *(See TDR, December 7, 2015.)*

After learning that Quest Diagnostics Incorporated had offered to waive fees for a physician in Florida, THE DARK REPORT asked Sherrin to comment. "This is a complicated area of law and laboratory operations, and there is much room for misinterpretation," he said.

Sherrin noted that the **Office of Inspector General** of the federal **Department of Health and Human Services** has issued two opinions on the practice of waiving fees. Attorneys for clinical labs often disagree on how to interpret those opinions.

For Sherrin, however, the bottom line is clear: clinical labs that offer to waive patients' fee should not assume they are free from risk simply because they believe that they are not providing a direct benefit to referring physicians.

Fee Waivers Will Proliferate

"It's important to understand that policies such as the Quest waiver of charges letter will proliferate in the industry because it's a matter of survival for laboratories that are kept out of participation agreements due to exclusive contracts," he explained. "This is not a life or death problem for Quest, but it is a life and death problem for many community clinical laboratories that are increasingly being shut out of

business by managed care plans and insurance programs that limit network participation to one or a few laboratories.

"In my opinion, the attention should not be on prosecuting smaller laboratories that have to adopt competitive measures to stay in business," noted Sherrin. "Instead attention should be devoted to stopping this practice of exclusive managed care contracts that are based purely on price, and that do nothing to enhance the quality of services to patients.

"One other issue to keep in mind is that the Anti-Kickback Statute deals with referrals that are paid for under the Medicare or other federal healthcare programs," he advised. "Since the Quest letter relates to managed care programs, Quest is not dealing with Medicare referrals. So, the question under the federal Anti-kickback Statute is whether this waiver of private pay charges induces the referral of Medicare or other federal healthcare business. That is not an easy burden for the OIG to prove.

"And, it brings up another issue, which is the risk—not from a federal anti-kickback prosecution—but from a civil action or false claims lawsuit being brought by a commercial insurer against a lab company, such as what **Aetna** and **Cigna** recently have done," advised Sherrin. "These lawsuits depend on laws in individual states. The theories in these lawsuits are interesting, innovative, and—in many ways—more troublesome to labs than the possibility of a federal anti-kickback prosecution."

Insurers Becoming Proactive

Clinical lab executives and their legal advisors should take notice of Sherrin's comments. He is pointing out that health insurers are becoming more proactive in pursuing non-participating labs that employ billing practices that, insurers claim, undermine their plan relationships with members. This includes more aggressive audits of claims, and, as Sherrin noted above, an increased number of lawsuits in which a health insurer is suing a lab company to recover payments it asserts were the result of false claims arising out of waivers of patient responsibility, whether copays, deductibles, or even balance billing.

"There has been much more activity in this area than in federal anti-kickback prosecutions," he added. "That is why I would caution laboratories to seek legal guidance on these potential liabilities, with a concern that is as much or more than their concerns with federal prosecution."

Managed Care Risks

Having addressed the potential risks labs face from managed care plans, Sherrin then turned to the issues related to OIG Advisory Opinion 15-04, which the Office of Inspector General issued last year in response to a request from an unknown lab with operations in many locations throughout an unnamed state. In the opinion, the OIG said a lab offering to waive such fees may run afoul of anti-kickback laws.

"Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General ("OIG") could potentially impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement," the OIG said in its opinion.

Sherrin noted that Advisory Opinion 15-04 does not definitively oppose such arrangements. "It also does not change what the OIG had said when it issued a special fraud alert on the subject in 1994, known as 'Routine waiver of Medicare Part B copayments and deductibles,'" he said.

"I do not find 15-04 to dramatically change the approach of the OIG from the 1994 Special Fraud Alert," he said. "Labs need to understand that the Anti-kickback Statute prohibits remuneration intended to induce referrals of services payable by a federal healthcare program. There is no question in my mind that the purpose of the Quest waiver letter is to induce referrals. By itself, that is not illegal, a factor commentators often overlook.

"So the question becomes whether the waiver of charges to the patient and the health insurance plan results in any remuneration to the referring physician," Sherrin continued. "That is what the 1994 Special Fraud Alert addressed, and it discussed ways in which the physician might financially benefit from a waiver of charges.

"A special fraud alert is designed to address a problem that is of increasing concern nationally to the OIG," he observed. "It is not addressing a particular laboratory or provider's situation. It is designed to give guidance to the industry.

Purpose Of Advisory Opinion

"An Advisory Opinion, such as 15-04, serves a different purpose. It tells a specific provider (that seeks an opinion, called a requestor) whether that provider is immune from, or at some risk of, prosecution under the specific facts the requestor presents," Sherrin explained. "In 15-04, the OIG recognized first that the arrangement would not fit within a safe harbor.

"Thus, the next question the OIG had to answer was whether it could give an assurance to the requestor laboratory that it would not face any risk of prosecution under the Anti-Kickback Statute, or the Substantially-in-Excess law," he stated. "The OIG opined that it could not give that immunity because there was a possibility that the physician could receive some remuneration. Further, the OIG did not find an overriding clinical or cost ben-

Some State Laws Address Waiver of Charges Issue

INDEPENDENT OF FEDERAL LAW, several states have statutes that address inducements and kickbacks. One attorney who saw the waiver of charges letter given to the Florida doctor by Quest Diagnostics is J. Marc Vezina, of the **Vezina Law Group** in New Orleans and Birmingham, Michigan.

In a story THE DARK REPORT published on December 7, 2015, Vezina said that the letter could be the basis for a False Claim Act violation, and possibly could be a violation of Florida state insurance rules and regulations. "My preliminary analysis is that this is a straight kickback arrangement—nothing more, nothing less," Vezina declared. "This is clearly an arrangement in which Quest is driving market share, and therefore utilization, in exchange for waiving patients' fees. In that way, the letter plainly describes a kickback arrangement that could be illegal under the Anti-Kickback Statute. Quest Diagnostics is saying, 'If you give us your market share we will waive the fees for your patients.'

"An out-of-network laboratory can benefit itself and the client physician if it waives the patients' charges and has the physicians continue to refer patients to it," he noted. "First, the arrangement obviously benefits the lab because it gets work it probably wouldn't get because it is not an in-network provider. Second, it benefits the plan member who is not charged a fee for going out of network. Normally, a patient going out of network would be charged a fee for doing so and that fee usually is much higher than going to an in-network laboratory."

Our December 7, 2015, issue included a statement by Wendy H. Bost, Director, Corporate Communications at Quest, on this matter. She said, "Quest Diagnostics carefully evaluates our billing practices and has a vigorous compliance policy designed to comply with applicable laws and regulations. We have reviewed the March 2015 OIG advisory opinion (AO 15–04). Our position on this recent AO is aligned with that of our trade group, the American Clinical Laboratory Association (ACLA)."

efit to the arrangement that would outweigh the possibility of an anti-kickback violation. This OIG advisory opinion does not change the law at all.

"The factor in 15-04 that is disturbing is the type of benefit that the OIG says it could consider in deciding whether there is unlawful remuneration," Sherrin added.

One month after the OIG issued its Opinion 15-04 in March 2015, the **American Clinical Laboratory Association** wrote to the OIG to say it had serious reservations about the opinion and that the opinion contained "novel theories" that could be misapplied to labs using "otherwise permissible arrangements." The ACLA referred to a federal court case, *U.S. v. Hagstrom et al*, (No. CR-04-120-R, Dec. 28, 2004), that was similar.

Seeking Precedent

On this issue, Sherrin stated, "The ACLA letter is correct in that the Hagstrom federal court case in 2004 held that this sort of benefit would not constitute unlawful remuneration under the Anti-Kickback Statute. The problem is that there are really no other decisions from courts that address this question, and the OIG has never issued any statement that it would not consider these types of benefits to be unlawful remuneration.

"I do not agree with the ACLA letter, however, to the extent that it overstates the meaning of 15-04, and that it has reversed the 1994 Special Fraud Alert," he added. "Basically, 15-04 says that each case has to be viewed individually, and there is no bright-line rule about what charges can be waived and what cannot be waived. The government would still have to prove that there was remuneration to the referring physician."

So, now the question is whether Opinion 15-04 prohibits Quest Diagnostics from waiving fees, as it offers to do in the letter to the Florida physician. "I don't think the waiver letter goes against 15-04, because it requires the referring physician to certify that he or she receives no financial benefit as a result of the waiver," noted Sherrin. "The problem is that 15-04 does not lay out what can constitute a financial benefit or unlawful remuneration.

Much Uncertainty

"And, as we can see from the 1994 Special Fraud Alert, the Hagstrom decision, 15-04, and the ACLA letter, there is much uncertainty about what constitutes remuneration," noted Sherrin. "Therefore, while the Quest letter purports to try to obtain a certification of compliance with the law, it will not insulate the parties from prosecution if the OIG decides to interpret remuneration much more broadly than Quest does."

Sherrin also disagreed with another statement in the letter from ACLA. "I don't think the ACLA letter correctly identifies an increased risk of prosecution," he wrote. "This is because 15-04 tells one laboratory that its arrangement could potentially generate illegal remuneration, but the OIG does not have enough information upon which to give a definitive opinion.

"The concern with 15-04, which the ACLA letter correctly points out, is that it specifically identifies forms of benefit that, to the OIG, might constitute remuneration that were not previously identified, and for which there is very strong argument that it would not be remuneration. So what 15-04 does is to tell the lab industry to be careful, and not to assume that just because the laboratory is not directly benefitting the physician financially, it is free from risk," Sherrin wrote.

In conclusion, he added, "The questions for clinical labs are these: How big is the risk, and how risk adverse are the parties involved?" TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Like the Sword of Damocles of Greek myth, market price reporting by labs under the Protecting Access to Medicare Act (PAMA) continues to hang over the heads of the nation's clinical laboratories. However, instead of a threat, PAMA market price reporting may soon become a reality. News reports indicate that, as of April 21, the White House **Office of Management and Budget** (OMB) had begun its review of the final rule as written by the federal **Centers for Medicare & Medicaid Services**.

MORE ON: *PAMA Price Reporting*

A date for implementation of market price reporting for lab tests has not been announced. Congress had mandated that the final rule be released by June 30, 2015, so CMS is almost a full year behind that timetable. Section 216 of the PAMA law establishes January 1, 2017, as the date when CMS is to implement new prices determined by the market price data submitted by labs.

FASTING FOR BLOOD CHOLESTEROL TEST

Overnight fasting is not needed for a blood cholesterol test. That is the recomendation of the **European Atherosclerosis Society** and the **European Federation of Clinical Chemistry**. Details of the recomendation and the study supporting it were published in the *European Heart Journal* last month. (*http://tinyurl.com/zb6249b*)

TRANSITIONS

- Mark Powelson was promoted to President and CEO of **XCR Diagnostics** of Park City, Utah. Prior to joining XCR, Powelson was with **DeNovo Sciences**, **HandyLab**, **Gen-Probe**, and **Boehringer-Manheim**.

- **Sequenom** of San Diego, appointed Glenn Magnuson as Vice President of Sales. He previously held executive positions at **T2 Biosystems**, **Thermo Fisher Scientific**, **Cytyc Corporation**, and **Abbott Diagnostics**.

- **Human Longevity, Inc.**, of San Diego promoted Kenneth Bloom, MD, to President, where he now reports to Craig Venter, PhD, HLI's CEO and co-founder. Bloom formerly served at **Clarient** and **US Labs**.

- Roberta Provencal died suddenly last month at age 62. She was Executive Director, Laboratory and Outpatient Rehab at **Catholic Medical Center** in Manchester, New Hampshire. She had previously held leadership positions in the laboratories of **Concord Hospital**, **Brockton Hospital**, and **Elliot Hospital**.

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DARK DAILY UPDATE

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

...the emerging business of brokering healthcare data. Third-party brokers represent an opportunity for labs to dollarize their lab test data, but issues of how to anonymize data and protect patient privacy need to be resolved.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, May 23, 2016.

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