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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...

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Hospital CEOs Have Nothing to Fear from Theranos

FOR MORE THAN TWO YEARS, **Theranos**, the lab testing company that says it intends to disrupt the clinical lab industry, has been the subject of cover stories in many prominent consumer and business publications. Its masterful public relations campaign seems to have touched almost every hospital and health system CEO in this country.

How do I know this? Because, during the same two years, everywhere our editorial team has traveled, one of the first questions we get from pathologists and lab administrators is about THE DARK REPORT's opinion of Theranos and its goal of disrupting the clinical lab industry. Invariably, during these conversations, the pathologists and lab executives will mention that they are regularly asked by their hospital CEOs and C-suite administrators about Theranos and its potential to disrupt the finances of the hospital and its outreach laboratory.

Until September 15, nearly all the media coverage of Theranos was positive and the theme of finger-stick collection, small specimens, multi-analyte tests with results in four hours, and a cost that is half of Medicare Part B clinical lab test fees, was accepted without question by such respected news organizations as *Fortune*, *Wired*, *USAToday*, and *New Yorker*. Given this media acceptance, why would the typical hospital CEO have any reason to question the assertions of Theranos and its CEO, Elizabeth Holmes? Add to this media blitz the highly-publicized agreement last spring between Theranos and **Cleveland Clinic**, and hospital CEOs had every reason to consider that Theranos could be a threat... if not a potential ally.

It is stunning at how quickly Theranos has turned from an object of media adoration to the subject of tough investigative reporting. Credit *The Wall Street Journal* for investing the time and money necessary to conduct a detailed probe into Theranos and the performance of its diagnostic technology. Following the publication of its front-page stories in September, other news outlets have begun their own investigations of Theranos.

As a consequence, the bloom seems to be off the Theranos rose, at least as far as the press is concerned. And, as you will read on pages 3-6, an undisclosed agreement between Theranos and **Safeway** is unraveling, all because Theranos' diagnostic technology may not be performing to expectations. Thus, it may be safe to say that hospital CEOs may not need to worry about Theranos after all. TDR

Might Lawsuits Come Next in Theranos Story?

Grocery store operator Safeway spent $350M to build blood collection centers in 800 of its stores

CEO SUMMARY: Recent disclosures in the news indicate that an agreement between Theranos and Safeway has gone sour—after Safeway spent a third of a billion dollars to fulfill its part of the collaboration! Reporting by The Wall Street Journal claimed that Theranos and Safeway are negotiating over this situation. If the two parties cannot agree in this matter, would Safeway's owners file a lawsuit. In response to the Journal's reporting, Theranos said it was "inaccurate and defamatory."

FOR TWO YEARS, both CEO Elizabeth Holmes and **Theranos**, her lab testing company, have been the darlings of the national media. A procession of cover stories in prominent magazines hailed her as an entrepreneurial genius who developed revolutionary diagnostic technology that would enable her company to disrupt the entire clinical lab industry.

That positive news spin may have ended on September 15, when *The Wall Street Journal* published the first of several front page exposés that described serious issues inside the highly-secretive Theranos. In response to the facts and questions about Theranos raised by reporter John Carreyrou in his investigation, a number of additional issues and concerns about Theranos have been published by major newspapers and business publications. Theranos and Holmes have scrambled to respond to the negative news coverage. They vigorously challenge the accuracy of the reporting and those statements can be found on the Theranos website at *www.theranos.com*.

In our previous issue, we provided a useful overview of issues concerning Theranos that are of specific interest to pathologists, lab administrators, and hospital executives. Carreyrou identified these points in his stories published between September 15 and October 23. *(See TDR, October 26, 2015.)*

Last week, Carreyrou and the Journal published another bombshell about Theranos. On November 10, the Journal published a story that claimed **Safeway**

had spent $350 million to build blood collection centers in as many as 800 of its grocery stories across the United States as part of an agreement it had with Theranos.

$350 Million Price Tag

Carreyrou wrote, "The plan called for Safeway to build upscale clinics that would house Theranos's blood analyzers and provide patients with rapid test results, according to current and former Safeway executives. The $350 million price tag was equivalent to more than half of Safeway's net income of $596.5 million in 2012. Safeway had revenue of $44.21 billion. Safeway also invested more than $10 million in Theranos, one former Safeway executive said."

As part of this story, the Journal published a response by Theranos about the report of an agreement between Theranos and Safeway. The WSJ noted, "In an email Tuesday, Theranos's general counsel, Heather King, said: 'We don't comment on discussions with other companies. The questions and information you have presented... are inaccurate and defamatory.' She declined to comment on the claims by former Safeway executives." A spokesperson from Safeway declined to comment to the Journal.

The Journal made another stunning claim about the perceived failure of Theranos' proprietary lab testing technology to produce accurate and reproducible lab test results for specimens collected from Safeway employees.

Drawing Blood Twice

Carreyrou wrote, "In an initial phase of the project, Safeway had Theranos conduct blood testing at the headquarters clinic [in Pleasanton, California], current and former Safeway executives said. Theranos often drew the same employee's blood twice, first with blood from a finger prick and then the traditional method of a needle in the arm, according to one former Safeway executive."

This description of how Theranos collected two specimens—a capillary blood specimen by fingerstick and a venous blood specimen by venipuncture—from Safeway employees mirrors the experience of THE DARK REPORT's editor when visiting the Theranos Wellness Center in the **Walgreens** in Palo Alto, California last May. *(See TDR, May 11, 2015.)*

The Journal further described issues associated with the lab tests Theranos performed for employees at the Safeway corporate clinic. It stated that "the former [Safeway] executive said he worried that Theranos's finger-prick process was still a work in progress. 'If the technology is fully developed, why would you need to do a venipuncture?' this person said, using the term for a traditional blood draw."

Different Test Results

The Journal continued, "The concerns deepened when Theranos' test results for several Safeway employees differed from the results the same employees got from other laboratories, according to the former executive. Another former Safeway executive confirmed those recollections.

"It isn't clear how many Safeway employees got blood tests from Theranos or whether the varying results came from finger-prick or venous tests. One Safeway executive got a frighteningly high result from Theranos on a test to gauge his prostate-specific antigen [PSA], according to two former Safeway executives. They said the test suggested that the executive had prostate cancer. Retesting by another lab came back normal," wrote the Journal.

Carreyrou made another notable disclosure involving Theranos' reluctance to put its proprietary lab test analyzer into Safeway stores. He wrote, "Theranos also backed away from putting its blood analyzers in Safeway's clinics so patients could get the results quickly, the current and former executives said. Instead, Theranos said blood samples collected at

Safeway would have to be shipped to a central lab for analysis, according to the former executives."

Pathologists will recognize the significance of this situation, if it is true. In order to perform clinical laboratory testing within a Safeway grocery store, Theranos would need to comply with regulatory requirements of the **FDA** and the Clinical Laboratory Improvement Amendments (CLIA) that are supervised by the **Centers for Medicare & Medicaid Services**.

Labs In Grocery Stores

To comply with these federal laws, Theranos would have to gain clearance or approval from the FDA for use of these analyzers for clinical testing purposes for waived or complex testing and/or offer these lab tests to patients by operating a CLIA-certified complex laboratory that performs LDTs in each Safeway store.

To meet CLIA requirements for operating a complex clinical lab doing LDTs, Theranos would have to staff a certified clinical laboratory scientist/medical technologist at each of the 800 Safeway clinics and each of these labs would need a physician as the medical director on the CLIA license for this site.

Lab Costs Vs. Revenue

Pathologists recognize that such arrangements would make it prohibitively expensive for Theranos to operate a CLIA-licensed lab in each Safeway store This is because the daily volume of lab tests to be performed would fall short of the number needed to cover the costs of operating that lab facility. Further, because Theranos prices those tests at just 50% of Medicare Part B clinical lab test fees, it generates substantially less revenue per test than a typical clinical lab.

It is a major claim that Safeway invested more than a third of a billion dollars to build blood collection centers in 800 stores as part of its agreement with Theranos. The Journal said the two compa-

Medical Director Needed For Theranos' CLIA Lab

ONE RECENT NEWS STORY ABOUT THERANOS that raised eyebrows among some pathologists and lab administrators was the disclosure on November 5 by *The Wall Street Journal* that a dermatologist was serving as a part-time medical director of Theranos's CLIA-licensed laboratory in Newark, California, since early this year.

This dermatologist is Sunil Dhawan, MD, whom the Journal describes as a "dermatologist without a degree or board certification in pathology or laboratory science... Dr. Dhawan, 56 years old, meets federal and state requirements to be a lab director because he is a medical doctor and has experience overseeing a lab. Theranos said he has supervised the lab affiliated with his dermatology practice for over 21 years."

The Journal also stated that "Diagnostics startup Theranos Inc. is seeking to hire a laboratory director to oversee one of its key facilities amid questions raised in laboratory circles about the qualifications of a physician who now runs the lab."

The timing of Dhawan's arrival as medical director of the Theranos CLIA-licensed lab is consistent with reporting by THE DARK REPORT that the board-certified clinical pathologist who was the previous full-time medical director of the Theranos CLIA-licensed lab had left the company in December 2014. That pathologist was Adam Rosendorff, MD. *(See TDR, January 26, 2015.)*

In recent years, Theranos has gone through several medical directors for its CLIA lab. Because of the restrictive non-disclosure agreements that Theranos requires of all its employees, these individuals, including former medical directors, cannot reveal that they once worked at Theranos. Commonly, their resumes and career summaries simply note that they worked at a biotech company for the dates when they were employed at Theranos.

Theranos Claim of Revenue from Pharma Firms Investigated by Reporter from the Financial Times

DID THERANOS EARN INCOME by providing its proprietary lab tests to pharmaceutical companies since its founding in 2003? That's one statement made multiple times in news profiles of Theranos and its CEO, Elizabeth Holmes, over the past two years.

Now, no less than the *Financial Times* has investigated this aspect of the Theranos story. On October 23, FT reporters David Crow and Adam Samson reported, "Several articles about the company, including a profile of Ms. Holmes in the *New Yorker* in December, have said that the company 'earned income from large pharmaceutical companies, including **Pfizer** and **GlaxoSmithKline**, which use its tests when they are conducting clinical trials on new drugs.' A spokesperson for Pfizer said: 'We've done only very limited historical exploratory work with Theranos through a few pilot projects, and we do not have any current or active projects with them.' 'I cannot find any evidence that we've done business with them in recent years,' said a spokesperson for GSK.'"

Another insight about the relationship Theranos may have had with pharmaceutical companies in past years can be found in a comment posted on a *Wall Street Journal* blog, at this url: *http://tinyurl.com/ndudj3k*.

This was posted on October 21, when Theranos CEO Elizabeth Holmes spoke at the WSJDLive 2015 conference in Laguna Beach, a week after *The Wall Street Journal* published its investigative stories about Theranos.

The commenter was identified as EX PHARMA and wrote: "I worked for **AstraZeneca**... Theranos tried to pitch pharma on 'Adaptive Clinical Trials' with the idea of collecting $100M strategic agreements... and saving pharma billions in clinical trials for pharma... trouble was the technology didn't work at all—the assays didn't work and the informatics didn't work. Pharma didn't bite strategically nor were any of the pilots extended. There was an apparent transformation [at Theranos from a business strategy of serving pharma] into a direct-to-consumer diagnostic company."

THE DARK REPORT was unable to find any response by Theranos to this reporting by the *Financial Times*, although the company has strenously pushed back against claims its technology has not lived up to expectations. Additionally, the blog comment by EX PHARMA reproduced above is unverified.

What is significant about this reporting and the blog comment is that they are examples of how journalists and others are now questioning the statements and assertions Theranos made in the many news stories and company profiles that were published over the past two years. As the reporters from the *Financial Times* discovered, when asked, officials at GlaxoSmithKline and Pfizer did not confirm the claims made by Theranos.

nies were negotiating to resolve this issue. What the Journal did not report is that Safeway changed ownership this year.

On January 30, an investor group led by private equity firm **Cerberus Capital Management** bought Safeway and merged it with **Albertsons**, which it purchased in 2006. Next, on October 6, Cerberus pulled an attempted $2 billion initial public offering (IPO) for Albertsons (and Safeway) because of unfavorable conditions in the stock market. Then, on November 10, the Journal did its story about the agreement between Safeway and Theranos.

The newly-published claims of this deal and the money spent by Safeway to build patient service centers in its grocery stores may further complicate Theranos' business plans going forward. Further, since unhappy partners often sue each other, might lawsuits be part of the next chapter in this story? TDR

Compliance Update

Tox Lab Millennium Pays $256M to DOJ, Files For Bankruptcy

Whistleblower lawsuit alleged Millennium induced doctors to order unnecessary urine tests

IN ANOTHER MAJOR LAB FRAUD CASE, toxicology lab company Millennium Health will pay $256 million to settle allegations in a whistleblower lawsuit that it overbilled federal healthcare programs for unnecessary lab testing. Just 22 days after this agreement, **Millennium Health** filed a petition for a pre-packaged Chapter 11 bankruptcy on November 10.

In papers submitted to the U.S. Bankruptcy Court for the District of Delaware, Millennium said it plans to reduce its debt under a $1.75 billion credit agreement it signed last year. Millennium issued a press release stating "It contemplates, among other things, a reduction in the company's debt by more than $1.15 billion and a contribution of $325 million by current equity holders. As a result of the restructuring, the lenders will become the new owners of Millennium."

Settlement With DOJ

On October 19, the U.S. Department of Justice announced the agreement with Millennium Health, formerly **Millennium Laboratories**. The company agreed to pay the $256 million to settle alleged violations of the False Claims Act. It was alleged that Millennium billed Medicare, Medicaid and other federal health care programs for medically unnecessary urine drug and genetic testing. The DOJ further alleged that Millennium provided free point-of-care supplies to physicians who agreed to refer laboratory tests to Millennium.

As part of the settlement, Millennium agreed to enter into a five-year corporate integrity agreement (CIA) with the federal **Department of Health and Human Services' Office of Inspector General**. Under the agreement, Millennium must hire a compliance officer to monitor day to day compliance and report to the OIG at least quarterly. On November 3, Millennium announced the hiring of Darrell W. Contreras, as its new Chief Compliance Officer.

Excessive Urine Drug Tests

In part of the settlement, Millennium will pay $227 million to resolve False Claims Act allegations that involved billing federal health care programs for excessive and unnecessary urine drug testing from January 1, 2008, through May 20, 2015, the DOJ alleged. Millennium had physicians order excessive urine drug tests by promoting custom profiles that were, in effect, standing orders that caused physicians to order large numbers of tests without assessing each patient's needs, the DOJ said.

Millennium also provided free point-of-care urine drug test cups to physicians on the condition that they return urine specimens to Millennium for additional testing, a violation of the Stark Law and the Anti-Kickback Statute, the DOJ alleged.

In addition to paying $227 million, Millennium has also agreed to pay $10 million to resolve allegations that it submitted

false claims to federal healthcare programs from January 1, 2012, through May 20, 2015, for what the DOJ said were routine genetic tests, again without assessing individual patient's needs, the DOJ alleged.

The San Diego-based laboratory also will pay $19.2 million to the federal **Centers for Medicare & Medicaid Services** to resolve administrative actions related to Millennium's urine drug test billing practices, the DOJ said.

One of the original cases began in 2012 when two whistleblowers and **Omni Healthcare**, a large physician group in Melbourne, Florida, alleged that Millennium was violating the federal False Claims Act. The DOJ joined the case and agreed to pay 15% of the $227 million plus interest from the settlement to the whistleblowers for the urine drug testing claims. Omni alone will be paid $1.48 million of the $10 million plus interest from the settlement for the genetic testing claims, the DOJ announced.

Attorneys Describe The Case

J. Marc Vezina and Monica P. Navarro of the **Vezina Law Group** in Birmingham, Michigan, and New Orleans, represented the whistleblowers and described the details of the case, including the custom-order profiles. "By using the custom-order profiles, Millennium was trying to make it easy for the doctors to order excess tests," he said in an interview with THE DARK REPORT. "But those profiles ran afoul of Medicare because they were doctor specific and not patient specific.

"The doctor's custom-order profile was created regardless of whether the doctor had one patient or 300 patients," noted Vezina. "So every patient who came in was subjected to a battery of unnecessary tests. For example, a patient taking Xanax would be tested for methamphetamines, Vicodin, cocaine, angel dust, and PCP, and many of those drugs are uncommon among Medicare patients. Clearly, this is not good clinical practice.

"Also, Millennium ran confirmatory tests on everything positive or negative," he stated. "Basically they were running tests to confirm negative findings by using the custom order profiles. Millennium was actively promoting confirmatory negatives in part because they ginned up homemade medical evidence to show that point-of-care tests are unreliable. For Millennium, this scheme was a hell of a good business model.

Lab Test Order Forms

"Millennium had their sales reps walk through physician offices and hand them order forms that were already filled out," Vezina explained. "They know that doctors are very busy and so they'd stick the forms in the doctor's face and ask the physicians to sign them and some did.

"In addition, a lot of doctors needed some incentive or push and so Millennium would offer to give them free point-of-care test cups in situations where Millennium's competitors were all charging for the POC cups," he added. "That might have been a small portion of the fraud but it helped to drive a lot of business to Millennium."

The physicians at Omni noticed the fraud in part because it's a large multispecialty group that operates two of its own clinical labs, Vezina said.

Agressive Marketing

Many pathologists and lab managers working in the labs of hospitals and health systems are unaware of the widespread use of aggressive marketing practices in the toxicology and pain management sectors of the lab testing industry that many consider to be violations of federal antikickback laws. This is why there are whistleblower lawsuits in this sector and why government and private payers are instituting more restrictive coverage and reimbursement guidelines for these types of lab tests. TDR

—Joseph Burns

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Market Update

Quest to Buy Outreach Lab from Hartford Health System

Hartford will keep inpatient testing and sell Clinical Laboratory Partners' outreach business

MORE LAB CONSOLIDATION is happening in Connecticut. Last week, **Quest Diagnostics Incorporated** announced it will purchase the outreach laboratory business of **Clinical Laboratory Partners.** CLP is a division of **Hartford HealthCare**, a health system with five hospitals in Connecticut.

After regulatory review, the acquisition is expected to become final early next year. Terms were not disclosed.

CLP is the current outreach laboratory services provider for the health system's physicians. Its main lab facility is in Newington, Connecticut, a suburb of Hartford. HHC's hospitals will continue to operate their in-house laboratories serving inpatients and outpatients.

CLP's outreach services will move to Quest's three rapid-response labs in Connecticut (in Stratford, Torrington, and Wallingford) and to Quest's more extensive lab in Marlborough, Massachusetts. Quest Diagnostics also acquired a number of CLP's patient service centers.

Hartford Healthcare CEO Elliot Joseph said the health system employs 570 workers in its lab outreach business. An undetermined number of those positions will be cut. Quest expects to add about 350 jobs, mainly in Connecticut, and will seek to identify candidates from CLP for these new jobs, added Joseph.

Since its formation in 1998, CLP has used Quest Diagnostics for its reference testing. Now, Quest and CLP will consider collaborating on population health and data analytics strategies. In an interview in 2011, CLP President and CEO James E. Fantus told THE DARK REPORT that CLP devoted significant resources to packaging test data into information-rich services for physicians and patients. *(See TDR, November 7, 2011.)*

Regional Lab Will Disappear

Quest Diagnostics' purchase of CLP removes another long-established regional laboratory company from the marketplace. When a hospital or health system decides to sell its lab outreach business, it is often motivated by the need for more working capital.

In the case of Hartford Health, the cash from Quest Diagnostics will bolster the health system's balance sheet. Its finances are stable, although **Moodys** downgraded some Hartford bonds in 2014, based on its 2013 financial performance, a need to catch up funding its pension plan, and a tougher operating environment.

With its purchase of CPL, Quest Diagnostics removes another tough competitor from this regional market while gaining additional specimen volume to run through its new lab facility in Marlborough. It built this lab after acquiring the lab outreach business of the **University of Massachusetts Worcester** in 2013. Quest had earlier purchased the lab outreach business of financially-strapped **Caritas Christi Health Care** in Boston in 2009. TDR

CEO SUMMARY: Arizona's new direct access testing law allows consumers and patients to have access to all laboratory tests without a physicians' order. But one lab company decided not to offer all lab tests to consumers. Instead, executives at Sonora Quest Laboratories recognize that, for some health conditions that are complex to diagnose, it is inappropriate to allow consumers to use these lab tests to screen themselves. For these types of tests, SQL encourages consumers and patients to speak to its pathologists or their physicians.

Arizona lab says limited DAT menu is in patient's best interest

DAT: Should Patients Have Access to All Laboratory Tests?

ACCOMMODATING ARIZONA'S NEW DIRECT ACCESS TEST (DAT) LAW that allows patients to get any test without a physician's order required the staff at **Sonora Quest Laboratories** (SQL) to make some difficult decisions about whether to offer to patients and consumers all clinical laboratory tests that it runs.

Before the law went into effect on July 3, SQL decided to limit the number of tests it offers patients on a direct access basis—in the best interests of patient care.

It's an interesting decision for a clinical lab. In a business built on test volume, Sonora Quest does not offer consumers and patients access to all laboratory tests, even though the new DAT law permits such consumer access.

Selecting which specific tests it would offer consumers through its DAT program was done in a reasoned and thoughtful way and was intended to be in patients' best interests, stated Robert Stern, MD, Medical Director of Sonora Quest Laboratories. By restricting access to some tests, the lab was, in effect, saying that giving access to all laboratory tests without a doctor's order would be a disservice to patients.

"Many laboratory tests are not appropriate as screening tests," explained Stern. "That is why, based on our best medical judgment, our DAT test menu includes those lab tests that we consider appropriate for a large number of patients and consumers to use.

"Before this law was passed, Arizona had a direct access testing law that allowed consumers to order any of about 50 lab tests identified in the statute," he said. "At the time this new law was proposed, we responded to a request for input from the bill's sponsor. Our suggestion was that the bill's sponsor consider expanding the list to about 100 tests rather than opening up the list to any lab test for direct access.

"We feel strongly that not every test is suitable for every patient in every situation," emphasized Stern. "For that reason, we chose to offer what we believe is a responsible panel of tests.

"Some tests are good general health screening tests that shouldn't lead a consumer too far astray," he said. "Other tests are recommended as screening tests for a large segment of the population and some are recommended for individuals with chronic medical conditions who want to take an active role in managing their condition.

"By giving consumers access to a curated list of tests, we can point them in the right direction," he added. "Our hope is to keep them from getting into too much trouble were they to order several lab tests and then wind up with results that could be difficult to interpret and could cause much anxiety.

Understanding Specificity

Stern explained the science used to select tests for SQL's Its My Lab ReQuest DAT menu. "Anyone who does laboratory testing and understands specificity, sensitivity, and predictive values knows that, if enough tests are done on a patient, there is a high probability of one or more of those results falling outside the reference range, even when the patient is perfectly healthy," he stated. "That's the nature of testing.

"We know that false positives can be the consequence of how clinical labs construct test ranges," he continued. "For most lab tests, the reference ranges capture 95% of normal, healthy individuals.

"That means if a panel of 20 tests is done on a single patient, there is a 65% chance that at least one of those test results will be outside the reference range, even if there's nothing wrong with the patient," noted Stern.

"This is why we decided it would be in the best interests of the average consumer not to offer all lab tests that exist through our direct access testing program," he commented. "By helping patients and consumers select lab tests that are appropriate,

it keeps the potential for misinterpretation to a minimum."

Given that decision, is Sonora Quest Laboratories worried that other labs will have a competitive advantage by offering all tests for direct access?

"No, this approach is part of the value proposition we offer to patients," noted Stern. "I'm happy to have these conversations with patients because this is something about which I feel strongly. Further, most physicians and most clinical laboratory professionals would probably agree with me on this point.

New Revenue Stream

"This is independent of the question that some labs ask about the new revenue streams that can result from DAT," he continued. "And the answer is, yes, absolutely, there is the potential for additional revenue from a DAT program.

"But Sonora Quest Laboratories is willing to forego potential revenue to do what it considers a more responsible job of helping patients and consumers manage their health, rather than simply offering them a product that will not always be appropriate."

Sonora Quest is the largest clinical laboratory company in Arizona, serving an average of 24,000 patients a day and running 57 million tests per year. To accommodate the DAT law, it was necessary for Sonora Quest to make changes in lab operations and workflow. For example, along with the existing capability to deliver lab test results to physicians, it needed to implement a solution for reporting test results to consumers who ordered their own lab tests.

"Ordinarily when a physician orders a test, the system is built so lab test results for his or her patients are reported either directly into that physician's electronic health record system, or by fax, or by other means they've selected," observed Stern.

"That's not what happens with direct-access testing," he said. "Since DAT results are being reported without a physician's signed order, the lab results must go to the patient and only to the patient.

"Arizona's DAT law specifies that a physician or other provider doesn't have liability for interpretation or action on those test results unless the doctor explicitly agrees to provide consultation to the patient," commented Stern.

"Our goal was to keep that in the forefront because we want to ensure that DAT testing works for patients and that physicians are not surprised by results for tests they did not order," he noted. "We didn't want to drop lab test results on physicians when they didn't expect them, didn't want to see them, hadn't asked for them, and didn't want the liability for acting on a lab test that they hadn't ordered.

"In fact, there seems to be some sensitivity about this issue among physicians here in Arizona," Stern added. "They do not want to be liable for the results of direct access tests. We recognize that sensitivity and we didn't want to possibly put ourselves between the patient and the physician.

"Thus, for example, a patient cannot send results from the patient portal to the doctor," he said. "The only way for a patient to send direct-access lab test results to a physician is to hand carry them or mail them.

Better Processes Needed

"In planning to support our DAT program, we recognized that we did not have robust processes for sending results directly to patients," he observed. "To address that problem, we developed a patient portal, which allows patients to retrieve their tests online.

"The beauty of the patient portal is that patients get the results of their direct access tests and can view the results of any prior lab test we've done for them since the portal's inception," explained Stern. "We can also send them results by email or postal mail if they prefer.

How Sonora Quest Laboratories Selects Tests It Considers Appropriate for Its DAT Menu

THERE ARE A NUMBER OF LAB TESTS for diseases and conditions that are difficult even for physicians to interpret accurately, given the clinical presentation of a patient. For this reason, Sonora Quest Laboratories does not offer these types of lab tests on its menu for its direct-access testing program.

One example is testing for celiac disease. "Many Americans today are interested in going gluten free in part because they are worried about celiac disease," stated Robert Stern, MD, Medical Director of Sonora Quest Laboratories in Tempe, Arizona. "That worry leads some to get celiac disease testing.

"It's a huge area of interest in the population right now," said Stern. "But the tests are difficult to interpret. Often I get calls from physicians who have ordered the tests and need help interpreting the results.

"The diagnosis is complex because the patient's IGA level (blood level of immunoglobulin A) will affect what the other test results mean when identifying celiac disease," he explained.

"To offer that test could have been a great moneymaker for the lab because so many people would have ordered it," stated Stern. "But we recognize the potential clinical consequences if such a test could be ordered by patients without a physician's order.

"Another example would be testing for Lyme disease, which is not endemic in Arizona," observed Stern. "Therefore, if a consumer gets the test and has not traveled to an area where Lyme disease is endemic, then a positive result is almost certainly a false positive.

"Once that consumer gets a positive result, they think they've got a problem and start worrying about what to do next," he added. "Usually that would trigger more lab testing and yet the initial test never should have been run in the first place.

"In laboratory medicine, it is called the 'Ulysses Syndrome' when a patient orders an inappropriate test, gets a result that he or she doesn't know what to do with and then gets more testing," he observed. "More lab testing leads to more results back.

"So, rather than helping to control healthcare costs, this kind of random or unselected testing can drive up costs—even though lab tests as a percentage of overall healthcare spending is relatively low," noted Stern.

"Remember, should a consumer order inappropriate tests and get results that require follow-up, additional lab testing would then be needed," concluded Stern. "Add physician visits to this scenario and costs can run into serious money. That's not good for anybody, particularly the patient who is now getting unnecessary lab tests and clinical care."

"There is another point to make about direct-access testing that is sometimes overlooked," he stated. "There may be cases where the patient or the consumer did testing for certain infectious diseases. By law, the clinical laboratory is required to report that data to the state health agency. This is to allow public health authorities to do the appropriate follow-up when needed. And that lab test data has the patient's name attached to facilitate follow up."

One issue many labs encounter when working with patients' test results is the ability to collect all lab test results so that the lab can use that data for population health management. DAT orders are segregated from all other results that are used in these reports. Another concern is whether keeping this data out of that pool of information that payers and others use to manage population health is potentially problematic.

That issue was important to Sonora Quest Laboratories. "How big the problem is will depend on how widespread direct access testing becomes," said Stern.

"And I don't think this is the end of the story because insurers are likely to want to have access to that data in some form, whether it's patient-identified or de-identified data.

"Will insurers want to work with some of their patients to get access to that DAT test data?" asked Stern. "And if they do, how will the insurers request that access? We don't want to be in the middle, but we are almost by default.

"Not only will the insurer be interested in using the data for population health management but the insurer might want to avoid duplicative testing," he observed. "As we were developing the processes needed to offer direct access testing, we kept in mind the concept that both laboratory testing and healthcare management are part of a team sport.

"Although the DAT law allows the patient to be the quarterback in terms of determining who gets lab test results, it's still important that patients share the results with their healthcare providers and we stress that point at multiple times in the process," he said.

When the state legislature passed the new direct access testing law and the governor signed the bill earlier this year, there was extensive news coverage of this event throughout Arizona. That is one reason why there is plenty of consumer awareness about DAT in the Grand Canyon State.

These developments coincided with the greater number of patients who are either uninsured and pay cash for their lab tests or patients who have high-deductible health plans and may need to meet out-of-pocket requirements of between $5,000 and $10,000 per year. Because of these factors there are many healthcare experts watching to see if patients and consumers in Arizona will embrace DAT and generate large volumes of direct access tests. TDR

—Joseph Burns

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DAT Means Collecting Money from Patients

IN ARIZONA, A DIRECT ACCESS TEST can be ordered by a consumer without a physician on the test request. For labs that offer DATs, this requires collecting payment from the consumer, typically when they have their specimen collected.

"At Sonora Quest Laboratories, we instituted changes in workflow in our 70 patient service centers to accommodate patients seeking direct access tests because these tests are handled a bit differently," noted Robert Stern, MD, SQL's Medical Director. "Patients who have physician orders usually pay with insurance and patients having direct access testing pay out-of-pocket.

"In fact, a patient ordering a direct-access test can't use health insurance to pay for that test," noted Stern. "Moreover, per the state law, the lab cannot bill that patient's insurance company and the patient cannot submit a claim to have insurance pay for the DAT test. However, the patient can pay by using a flexible spending account or health savings account, if he or she has one. The Arizona statute makes the patient responsible for paying for every direct-access test."

"Sonora Quest Laboratories researched the insurance payment issue," stated Christina Noble, Vice President of Business Development. "Our policy for DAT requires the patient to pay 100% at the point of sale," she said. "When patients come in with a DAT request, we ask that they pay 100% at that time.

"Additionally, we worked closely with those health insurers where we are in network to make them aware that Sonora Quest was offering direct access testing through our My Lab ReqQuest solution," continued Noble. "We instituted a procedure to specifically brand our receipts for DAT tests ordered by any patients. That way, if an insurer receives a request from a member to be reimbursed, it would clearly see that the lab testing was for direct access testing."

New Company Targets Lab Benefit Management

Avalon Healthcare Solutions gears up with contract to serve BCBS of South Carolina

CEO SUMMARY: Soon, the nation's newest laboratory benefit management company will begin working for Blue Cross Blue Shield of South Carolina. Avalon Healthcare Solutions committed to BCBSSC that it can save money off what the health plan has been spending on clinical lab testing. It will do so with algorithms supported by evidence-based medicine, good science, and transparency, the company said. Avalon also says it has a plan to help labs collect the copays and deductibles due from patients.

As a concept, clinical laboratory test benefit management is often discussed, but seldom implemented. That may soon change, due, in part, to the explosive growth in the number of expensive molecular and genetic tests physicians order.

One of the newest companies in this nascent field is **Avalon Healthcare Solutions, Inc.**, in Tampa. In July, Avalon announced its first contract when it agreed to develop a lab network for **Blue Cross Blue Shield of South Carolina**.

For BCBSSC, Avalon will manage laboratory benefits by applying evidence-based medicine and algorithms to manage the appropriate use of more than 4,000 lab tests.

The BCBSSC contract goes into effect this quarter. As part of this agreement, Avalon has promised to save the health plan a mutually agreed-upon amount over the contract term. What is of interest to clinical labs is how Avalon plans to achieve that goal in a manner that it says will be positive for the payer, physicians, patients, and the labs that provide testing.

To understand how this arrangement will affect labs serving BCBSSC members, The Dark Report interviewed Avalon CEO Bill Kerr, MD. As Avalon begins contracting with health plans and establishing clinical laboratory networks, Kerr explained the challenges Avalon faces.

Promoting Transparency

"It's my opinion that the best way to achieve these goals is to be transparent," commented Kerr. "That is the first priority. Let me explain how we plan to achieve transparency.

"As a physician, I understand what frustrates most providers—whether it be physicians, hospital labs, or independent labs—is to perform services and not get reimbursed," he said. "The challenge comes because all clinical labs invest substantial sums in staff, equipment and overhead to run every test ordered by a physician, yet payment for these tests comes from the health plan and from the member.

"Thus, when divergent needs exist, such as where the payer wants to lower costs and the lab test provider is con-

cerned about the effect lower costs will have on lab operations, it is essential that every aspect of the system be transparent," noted Kerr. "That means publishing the plan's medical policies and providing tools to make everyone aware of exactly how claims will be reimbursed.

Good Science Required

"Equally important is that medical policies be based upon good science and medicine," he continued. "As a lab benefit manager, Avalon is working to make good science the basis for all of its decisions. As that happens, the lab management program is likely to be more acceptable to all parties," said Kerr, a pediatrician who no longer sees patients.

"I started my clinical career with cancer research because my plan was to go into pediatrics and specialize in pediatric oncology," he explained. "To me, the science is very important to every decision any physician makes. And in labs today, there's an explosion in how science can measure what is happening in the human body."

Avalon was formed to help physicians do a better job of selecting the right lab tests so that patients get the best possible care. The additional benefit is that the cost of care is better managed.

"This emphasis on science is why we have a clinical advisory board that includes some of the best-known experts working in large academic labs," stated Kerr. "The process is to summarize the literature, including newly-published clinical studies. The board then adds its input and guidance.

"Medical policies are developed from this process," he added. "Those policies guide our decisions. The next step is to convert those medical policies into reimbursement policies. Then, this system will interpret our policies and apply them to each lab test claim.

"An important part of this process is to share those medical policies with both contracted labs in our network and with our health plan customers," said Kerr. "In addition, these policies will be accessible on the health plan's website so every referring physician can see the relevant medical policy, the supporting scientific literature, and how much the health plan will pay.

"This describes how Avalon will use good science and make it transparent," noted Kerr. "In this business, no provider wants a 'black box' that makes it tough to understand a health insurer's coverage and payment guidelines.

"I say that because, in addition to my work in pediatrics and oncology, I have worked for managed care plans for a number of years," he said. "This experience is relevant because managed care plans are Avalon's customers. On a list of benefits for a health plan, some lab tests may not be covered in certain situations. It is our role to help clarify those situations because we work on behalf of the plan that pays the bill.

Managing Test Panels

"At the same time, if the medical policy is based on good science, then we anticipate that most providers will have fewer questions about what is covered and what is not," emphasized Kerr.

Initially, one of the most active areas of lab benefit management will be routine testing, where some labs pack panels with unnecessary tests. While the vast majority of the program's medical policies involve working with rendering labs in adopting evidence-based payment policies, certain policies involving genetic testing will require prior authorization.

"There are some genetic tests that may be covered for one clinical condition, but not be covered for others," Kerr stated. "That is why it is essential to use the science to develop the policy, then apply that science and the policies in every situation so Avalon supports what is most appropriate for each patient.

"Another area that will be closely monitored involves high-cost tests, mean-

How Avalon Healthcare Solutions Plans To Identify High-Quality Labs for Its Network

CREATING A NETWORK OF CLINICAL LABORATORY PROVIDERS that can meet expectations for service, patient access, quality, and price presents Avalon Healthcare Solutions with some unique challenges.

"This process will start with an evaluation of each lab's past performance," stated Avalon CEO Bill Kerr, MD. "The first step is to review claims data and the past billing practices of a lab. We want to identify those labs with the least variation in lab performance. Everyone is familiar with the variation in healthcare and in provider performance.

Recruiting Top-quality Labs

"It is presupposed that all labs want to be high-quality, high-value labs," noted Kerr. "In truth, not all labs deliver high-quality results consistently. As a network manager, Avalon can treat all labs equally.

"However Avalon's goal is to recruit into its network only laboratories that meet the highest clinical standards and also deliver high value," he said. "The best of these labs already recognizes the need to move away from high volume and may already be helping client physicians improve how they utilize lab tests."

Clinical laboratories that join Avalon's provider network will enjoy increased lab test volume. "Every lab's performance and adherence to policies will be monitored over time," continued Kerr. "Labs that don't meet those standards will be dropped from the network while the best performers will see increased test volume."

Overutilization of lab tests is a recognized problem and clinical laboratories are in a position to contribute to improvement in this area. In its discussion with payers, Avalon is learning that health insurers want to manage utilization more actively. Kerr provided the example of test bundling.

"One metric that Avalon will monitor is how labs bundle services together into panels and how they bill for those services," he said. "Today, as we review claims data across multiple payers, we see physicians monitoring lipid levels.

"Depending on which clinical lab a physician is using, the lipid monitoring panel may contain six or seven analytes or it may have as many as 45 analytes!" observed Kerr. "Which panel is appropriate? Do we need all of those tests if we are monitoring lipid levels? Here is where medical policies based on sound science can help physicians deliver better care to patients.

"At the same time, Avalon and health insurers will not support reimbursement for those unneeded analytes," he emphasized. "As we see how certain labs bundle tests together, we will manage those panels carefully.

"As a consequence, Avalon is almost required to do some up-front clinical review to give an accurate determination to the physician and the laboratory as to whether these lab tests will be covered, given the patient's clinical presentation and whether the genetic test will contribute clinical value," explained Kerr.

"Thus, Avalon will be working with physicians and labs to make sure only appropriate genetic tests are ordered," he concluded. "Doing that up front is expected to eliminate much of the difficulties labs have with payers today."

ing genetic tests," he continued. "If we could find a way to create a simple and automated process to make coverage determinations of high-cost genetic tests, we would do that.

"The problem for physicians and payers is that the clinical scenarios are complex," noted Kerr. "An aggravating factor is that coding lags behind the rapid advances in clinical test technology."

Kerr then described what he called Avalon's "secret sauce" to make lab test benefit management go smoothly in everyday clinical use. "As pathologists know, clinical laboratories are in a very high transactional business and no one wants a lot of manual touches during any phase of the process, and that includes physicians, payers, and labs," he said. "Avalon's solution is to develop and incorporate algorithms that interpret the medical policies and support auto adjudication of lab claims on behalf of payers.

Use Of Algorithms

"One advantage of using good science and algorithms in our systems is that it keeps Avalon out of the exam room at the moment when the physician is with the patient," stated Kerr. "By design, Avalon will be transparent and invisible at that level. Our emphasis will be in helping labs simplify how their client physicians order lab tests while helping to ensure that, if the test is appropriate, the labs get paid.

"Our business approach has another important benefit for clinical labs," he continued. "As the number of payers working with Avalon expands, all the labs in our network will enjoy a consistent workflow across multiple payers and consistent payment policies from one payer to the next. That consistency alone should simplify a lot of processes for clinical labs and for referring physicians."

Avalon plans another service that will be welcome to those labs participating in its network.

"In addition to all the transparent policies and the real-time auto-adjudication of lab claims, Avalon will support labs in collecting copayments and deductibles from patients," emphasized Kerr. "As mentioned earlier, no provider wants to work and not get paid.

"Typically, clinical labs are required to collect copayments or deductibles," he explained. "They have to make a good faith effort to collect from each and every patient. That's a problem for labs, and Avalon can help labs solve that problem."

Avalon's Executive Team Comes from Insurers

WITH SUCH A LARGE NUMBER of expensive molecular and genetic tests now available for clinical care, it is not surprising that Avalon Healthcare Solutions was founded by executives from the health insurance industry.

CEO Bill Kerr, MD, was formerly the Chief Medical Officer at **WellCare Health Plans** and **Blue Cross Blue Shield of Florida**. Earlier he served with several other health plans.

President Jonathan B. Gavras was the Senior Vice President, Delivery System, and Chief Medical Officer of **Florida Blue**, Florida's Blue Cross and Blue Shield company. Previously, he had been a National Medical Director for **UnitedHealth Group** and also held positions at **Prudential Healthcare**.

COO Gordon Sween worked at UnitedHealth Group as the Senior Vice President of **Optum Retiree Exchange Solutions**.

CFO Greg Haddad was formerly the Vice President, Corporate Development, for WellCare Health Plans.

General Counsel Steve Morgan was the Vice President and Associate General Counsel for **Express Scripts**, one of the larger pharmacy benefit management companies.

On November 3, Avalon Healthcare Solutions announced that it had inaugurated "the initial phase of its innovative, comprehensive lab management program. The company has launched its national network of independent specialty laboratory providers offering physicians and their patients' access to high quality, specialized laboratory testing services." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Roper Industries, the owner of **Sunquest Information Systems, Inc.**, acquired two more lab informatics companies. On October 26, it announced a definitive agreement to purchase **Atlas Medical**, familiar to lab administrators as one of the main providers of connectivity solutions for clinical labs and pathology groups in the United States. Roper also signed an agreement to acquire **CliniSys Group Ltd.**, a significant supplier of laboratory information management systems in Europe. Because CliniSys supplies 2,000 laboratories in 34 countries, the acquisition is contingent on regulatory approval by authorities in Germany and the United Kingdom. When completed, the two acquisitions will make Roper and Sunquest one of the world's largest providers of lab information systems.

MORE ON: *Sunquest*

In 2014, Sunquest surprised many in the clinical lab industry when it acquired **Data Innovations** of Burlington, Vermont. Data Innovations has been a major provider of middleware and instrument connectivity solutions for clinical labs. Sunquest was itself acquired in 2012 by Roper Industries, which installed Matthew Hawkins as the new CEO of Sunquest and tasked him with developing a more aggressive growth strategy.

PATHOLOGY CHAIR

Starting January 2016, J. Stephen Dumler, MD, will become Chair of the Department of Pathology at the **Uniformed Services University of the Health Sciences' (USU) F. Edward Hébert School of Medicine**. He succeeds Robert Friedman, MD, who retired in 2014 after 34 years as chair of the department. Dumler will be responsible for an "expanded academic enterprise that aligns the academic and service work of the Department of Pathology at USU, the Department of Anatomic and Clinical Pathology at **Walter Reed National Military Medical Center** and the **Joint Pathology Center**, the successor organization to the former **Armed Forces Institute of Pathology**" Dumler is currently a professor in the Department of Pathology at the **University of Maryland School of Medicine**.

TRANSITIONS

- **Empire Genomics** of Buffalo, New York, announced that John J. Rushton, PhD, is its new Chief Operating Officer. Rushton has held executive positions at **PAML**, **Signature Genomics**, and **University of New Mexico Health Sciences Center**.

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Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...the pilot program at **UCLA Medical Center** to integrate genetic patient data into its **EPIC** electronic health record using **ActX**, a genomic data collector. The goal is to help physicians with decision support for precision medicine.

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

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 7, 2015.