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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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Is Pharmacogenomics Unaffordable for Payers?

ACROSS THE UNITED STATES, labs that perform pharmacogenomic tests complain that both government and private payers are reluctant to issue coverage guidelines and adequate reimbursement for these assays. Yet, this new class of diagnostic lab tests is the foundation of personalized and precision medicine.

Why are government and private health programs taking this tough stand on covering and paying for new pharmacogenomic tests? After all, there is universal agreement among physicians, experts, and healthcare policymakers that the future of modern medicine is to deliver personalized and precision medical services to patients.

At THE DARK REPORT, our investigation into this situation led to a surprising conclusion: Payers fear that the volume of pharmacogenomic tests ordered has the potential to become financially overwhelming. Said differently, if almost any patient who is a candidate for a prescription drug could benefit from a pharmacogenomic test—and the number of those patients is in the tens of millions—how could federal and private health programs find the money to pay for these tests when they are already struggling simply to fund current healthcare services?

If you accept this premise, then the story we report on pages 3-5 will make sense. It is about a pharmacogenomic lab testing company in Louisville that has just been hit with a $26 million repayment demand by the Medicare program. This demand is the result of an outside auditor denying 100% of the 30 pharmacogenomic test claims that it audited—then extrapolating that determination to all similar claims over almost three years.

Think about the math. In 2015, it is reported that 4.4 billion prescriptions were written in the United States. That's about 13 prescriptions for every man, woman, and child. Assume that just 20% of the U.S. population got a pharmacogenomics test before their doctor selected a specific therapeutic drug. That would be 60 million tests. At $200 per test, that would be $12 billion spent on pharmacogenomic tests in just one year! By comparison, Medicare pays $7 billion annually on Part B lab tests.

This example illustrates why health insurers are slow to make coverage determinations and even slower to pay claims for pharmacogenomic tests. Payers recognize the real possibility that a rapid expansion in physician use of pharmacogenomic tests could be the ultimate budget-buster! TDR

Medicare Audit Hammers Pharmacogenomic Lab

Lab hit with $26 million overpayment demand after ZPIC auditor denies 100% of sampled claims

CEO SUMMARY: After Pharmacogenetics Diagnostic Laboratory LLC was audited by a Medicare Zone Program Integrity Contractor (ZPIC), it faced a $26 million repayment demand. The lab company appealed and asked for a redetermination, then filed for Chapter 11 bankruptcy protection. These developments should be a concern to all labs offering pharmacogenomic testing to Medicare patients. This audit may be an early sign that ZPIC audits will be more aggressive.

FOR YEARS, CLINICAL LABS and pathology groups have feared the power that private auditors have under the Medicare Zone Program Integrity Contractor (ZPIC) program. Now a lab company in Louisville, Ky.—hit with a $26 million bill from a ZPIC—is in bankruptcy and fighting for its life.

The only details available about this case are contained in the documents filed on Nov. 8 by **Pharmacogenetics Diagnostic Laboratory LLC** (PGXL) to initiate a Chapter 11 bankruptcy in the U.S. Bankruptcy Court for the Western District of Kentucky. Officials at PGXL declined to discuss any aspect of this case.

The $26 million repayment demand by the Medicare program is only part of the story. The claims in question were for pharmacogenomic testing and the auditor ruled that 100% of the claims it inspected post-payment should be denied. THE DARK REPORT believes this is a significant development.

This audit fight might be an early sign that federal health programs consider pharmacogenomic tests—essential to the practice of precision medicine—to be a clinical service that would bust their budgets if tens of millions of Americans were candidates for this testing in coming years. Thus, could this audit be an early signal from federal health officials that they are not prepared to cover pharmacogenomic tests? *(See story on page 2.)*

Independent of that conjecture, every laboratory in the United States has reason to be concerned if the private contractors Medicare retains to audit clinical labs have the power to make such sweeping

assumptions during a random sample audit of lab test claims. This is true whether the audit is conducted under the Recovery Audit Contractor (RAC) program or the Zone Program Integrity Contractor (ZPIC) program.

Documents in the PGXL bankruptcy case explain in chilling detail how PGXL learned of the audit findings:

> *By letter dated October 4, 2016, CGS Administrators, LLC ("CGS"), the Medicare contractor for region J15 (Medicare Part B) issued an overpayment demand to PGXL. The overpayment demand is the result of an audit conducted by AdvanceMed, the Zone Program Integrity Contractor ("ZPIC") for Medicare Part B in Kentucky. AdvanceMed conducted a post-payment audit of thirty (30) patient records for claims with dates of service from January 1, 2012, through September 23, 2015. As a result of its review, AdvanceMed imposed a 100% denial rate for these claims, which it then extrapolated to the universe of claims submitted by PGXL during this same period. The extrapolation resulted in the $26,333,173.00 overpayment demand issued by CGS.*

Auditor's Methods Disputed

After examining records from 30 patients, the auditor declared all 30 to be falsely billed and then extrapolated to include all claims over almost three years to arrive at a staggering demand for overpayment of $26.3 million, the documents show.

PGXL officials disagreed with AdvanceMed's findings, its sampling methods, and extrapolation to reach the amount to be repaid. The lab company also began the administrative appeal process by filing a redetermination request with CGS on Nov. 3. CGS had until about Jan. 3 to issue a decision.

"Debtor believes that the ultimate liability, if any, will be significantly less than $26 million," the filing said. In the documents, PGXL described itself as a commercial and research laboratory that is working to bring pharmacogenetic drug sensitivity testing into the mainstream. The lab offers molecular diagnostic testing and interpretive services to physicians, clinics, and hospitals; has 21 employees; and expected gross revenue in 2016 of about $8.8 million.

Overpayment Demand

This ZPIC audit and outcome is significant. It means that the $26 million overpayment demand is an amount that equals a full three years of revenue for PGXL, a lab company that has been in business only 12 years! THE DARK REPORT is unaware of any precedent in the lab industry where a Medicare auditor has essentially declared such a high proportion of the lab's Medicare claims to be overpayments and subject to recoupment by the Medicare Program.

Pharmacogenetics Diagnostic Laboratory LLC, has been a pioneer in the fields of exome sequencing and pharmacogenomic testing. It was founded in 2004 by Roland Valdes Jr., PhD, along with Mark W. Linder, PhD. Both are professors of pathology at the **University of Louisville**.

Valdes serves as president of PGXL and is a tenured professor of Pathology and Laboratory Medicine and of Biochemistry and Molecular Biology at the University of Louisville's School of Medicine. Linder is PGXL's executive vice president of operations and a professor in the Department of Pathology and Laboratory Medicine at the University of Louisville and assistant director of Clinical Chemistry and Toxicology at the University of Louisville Hospital.

Diagnostic Informatics Tools

In an interview with THE DARK REPORT in 2012, Valdes explained PGXL's work to develop what he called "companion informatics" to estimate warfarin dosing to stabilize a patient. "Pharmacogenetics Diagnostic Laboratories is seeking to

Medicare's Zone Program Integrity Contractors Are "Most Serious" Audits Faced by Providers

IN AN ARTICLE DESCRIBING MEDICARE'S Zone Program Integrity Contractor (ZPIC) initiative, the **American Health Care Association** (AHCA) says: "The most serious audit or investigation that you can be involved with is with a ZPIC." The association represents long-term and post-acute care providers.

"The primary goal of the ZPIC is to identify cases in the Medicare program of suspected fraud, develop them thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and that any mistaken payments are recouped," said AHCA.

These contractors have no specified look-back periods and can make unlimited requests for documents, AHCA said. "ZPICs have the authority to suspend payments, recoup overpayments through extrapolation, refer the provider to the federal **Office of Inspector General** (OIG), and determine if the provider violated its participation agreement (with the federal **Centers for Medicare and Medicaid Services**)," it added.

CGS, the Medicare Administrative Contractor serving Kentucky, said that under the ZPIC program, fraud is defined as billing for services not furnished; billing that appears to deliberately seek duplicate payment; altering claims or medical records to obtain a higher payment; soliciting, offering, or receiving a kickback or rebate for patient referrals; and billing non-covered or non-chargeable services as covered.

develop similar diagnostic informatics tools for use with different drugs and in the treatment of different medical syndromes," Valdes said said in an interview with THE DARK REPORT. "Cardiovascular medicine is an area of interest, along with likely applications in oncology and psychiatry." *(See TDR, June 25, 2012).*

In response to a request by THE DARK REPORT, Valdes said he could not comment for this article.

Investment By Foundation

In March 2011, **University of Louisville Foundation Inc.** (ULF) contributed $1 million in capital to PGXL and became a part owner. "Debtor's membership interests are owned as follows: Dr. Valdes, 59.68%, Dr. Linder, 8.15%, and ULF, 32.17%," the filing showed. ULF has a potential maximum exposure of $4 million, according to reporting by Joe Sonka in *Insider Louisville*.

PGXL has assets of less than $1 million, liabilities of $10 million to $50 million, and between 200 and 999 debtors, the filing showed.

PGXL's largest creditor is **Stock Yards Bank & Trust Company**, which has a claim against PGXL for $3.5 million from a revolving promissory note issued Feb. 6, 2015. The note matured Feb. 6, 2016. "SYB granted certain extensions which amended the maturity date to Sept. 5, 2016," the filing said.

In September, SYB sent PGXL a default notice. The three owners of PGXL (Valdez, Linder, and ULF) have guaranteed payment of the note. "At the time of the bankruptcy filing, the amount of the SYB's claim under the note was approximately $2.975 million," the filing said.

Only a limited amount of public information is available about the bankruptcy case and PGXL's redetermination request with the Medicare program. Thus, it is too early to understand whether this ZPIC audit is an outlier event or the first example of more aggressive ZPIC audits that will happen as private auditing companies show up at clinical labs in other regions of the United States. **TDR**

—By Joseph Burns

PAMA Economics Drives Merger of Two Path Groups

➤Seattle pathologists see the need to be better positioned when CMS slashes reimbursement

➤➤CEO SUMMARY: Among the three chief reasons for the merger of CellNetix and Puget Sound Institute of Pathology, the most compelling was the need to address the challenges in the current reimbursement environment and to prepare for reductions in payment to pathologists expected in the coming years under the Patient Access to Medicare Act. CellNetix and PSIP also are seeking broader geographic reach and, like all pathology groups, need to invest in new technology.

FORWARD-LOOKING PATHOLOGISTS expect that reimbursement for anatomic pathology professional and histology services will continue to decline in coming years. The only question is how fast and by how much will these revenue reductions occur.

Recognizing the inevitability of less revenue for anatomic pathology, some pathologists are deciding that the best business and clinical strategy for financial survival is to act now—ahead of the coming reimbursement cutbacks—and merge together into ever-larger regional pathology supergroups. This strategy accomplishes several goals.

One, the larger specimen volume helps to lower the average cost-per-test. It also allows the pathology group to offer a bigger menu of in-house tests. This makes it easier for the pathology group to maintain margins as fees for technical and professional component services are cut back by Medicare and private payers.

Two, the larger case volume enables the regional pathology group to offer a wider mix of pathology subspecialty services. This helps the group bring in new hospital clients and expand the number of office-based physician accounts that it serves.

Three, the lower costs, greater subspecialty expertise, and expanded market share of regional pathology supergroups helps these groups obtain a greater number of managed care contracts on more favorable terms. This has the added benefit of preserving access to more patients because the regional pathology group remains an in-network provider for a much greater number of health insurance plans.

➤Gaining Strength in Numbers

These three business goals are among the reasons why two large anatomic pathology groups in the Seattle metropolitan area recently entered into a non-binding letter of intent to merge. **CellNetix Pathology & Laboratories, LLC**, and the **Puget Sound Institute of Pathology, PLLC** (PSIP) are completing their pre-merger due diligence and expect to close the deal in this quarter.

The merger would form one of the largest pathologist-owned private

anatomic pathology groups in the United States, the companies said. Financial terms were not disclosed.

In an interview with THE DARK REPORT, PSIP CEO Stewart Adelman identified three primary reasons for the merger and each one involves positioning the combined companies for the future. Those reasons are the need to invest in new technology while cutting costs, broader geographic reach, and preparing to deal with the expected reductions in payment for pathology services as a result of PAMA.

"The reimbursement environment already is challenging," Adelman said. "But when we looked at what to expect in the coming year as a result of PAMA, any further decline in payment will be that much more challenging.

Need to Reduce Costs

"We're trying to determine what will happen to reimbursement when CMS goes to market-based pricing under PAMA," he continued. "PSIP needs to retool the instrumentation in both its histology and molecular labs and—to finance that—we must reduce our costs. In addition, we will face lower payment when CMS introduces its new reimbursement scheme under PAMA in just 12 months, on January 1, 2018.

"I'm worried about having to compete with the pricing offered by **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** because the weighted-average calculation that CMS is prepared to conduct excludes the private payer test price data from most hospitals," observed Adelman. "That means bias is built into the calculations and this bias will result in a downward shift in pricing for most labs and pathology groups. The competitive challenge for labs like us is that Quest Diagnostics and LabCorp have lower costs and so can better survive the coming fee cuts to Medicare lab test prices."

Logic, History Were Factors In PSIP, CellNetix Merger

WHEN PATHOLOGISTS AND ADMINISTRATORS at CellNetix Pathology & Laboratories, LLC, and the Puget Sound Institute of Pathology PLLC (PSIP) considered the advantages of a merger, there were many obvious reasons to pursue the idea.

For one, each of the pathology groups has a core lab in Seattle and they are within three miles of each other. For another, the CellNetix core lab runs recent technology while some of the equipment in the core lab at PSIP is older and requires much more hands-on technical expertise, said Stewart Adelman, PSIP's CEO.

A significant leadership change at CellNetix last year opened the door to the idea, added Adelman. "That change made it possible for the two companies to start talking about the market here in Washington and what each lab company has for strengths and weaknesses in that market," he said.

In addition, Adelman and CellNetix CEO Kathleen Fondren have known each other for 30 years and each one started in the lab business as a med tech. "We both worked at **Northwest Hospital** in 1986," Adelman said. "I was the night shift supervisor of one at the first outreach clinical labs in the country and she was the supervisor on the afternoon shift. Knowing each other certainly helped to get the conversation started between our two pathology groups."

The need to be service- and cost-competitive was the first reason for PSIP and CellNetix to explore a merger. "The analysis at both our pathology groups was that it is better—if not essential—to be bigger," he continued. If a pathology laboratory information system can cost as much or more than $1 million, then how does a group of 23 pathologists (as we have here, including seven pathologists who are also partners at PSIP) handle that kind of expense?

"The costs of running a lab with the needed, state-of-the-art instruments and informatics are too high for smaller pathology practices," noted Adelman. "The pathologists at PSIP understood this basic economic fact. It was a key factor in their decision to explore merging with a larger pathology group in our region."

Unified, Larger Group

CellNetix CEO Kathleen Fondren agreed. "Merging CellNetix and PSIP benefits all the pathologists because the unified, larger group delivers lower costs, improved subspecialist coverage, and an expanded menu of complex molecular and genetic tests," she said. "In turn, this makes the merged group more competitive in ways that physicians, patients, and payers value. By bringing together two of the largest pathology groups in the Pacific Northwest, we are supporting the ongoing integration of clinical care and the delivery of personalized medicine.

"In addition, we will integrate our laboratories, IT systems and testing menus, which will allow us to further reduce our cost per test," she added. "Merging the two lab companies allows us to leverage our size to achieve efficiencies in operations. The laboratory industry has traditionally been very competitive in this region. Thus, ultimately, the merger positions us better for the future."

When combined, the two groups will have 67 pathologists, said Adelman. "But most pathology practices are smaller than either CellNetix or PSIP. If the average path group has fewer than six pathologists, I don't know how they'll survive into the future with the investment that's required. Another factor that no one talks about but that also drives up a pathology group's cost of doing business is new regulations. Compliance constantly costs us more money from one year to the next!

"To survive going forward, our opinion is that smaller groups have only two options," he explained. "One option is to merge into bigger pathology practices and consolidate their laboratories. The other option is for their pathologists to become employees of the hospitals and health systems that their groups are contracted to serve.

"The second significant reason for the merger is that it will give our combined group broader coverage geographically and that gives us strategic advantage," noted Adelman. "Right now, each organization provides pathology services to a major health organization. But there is a downside to this situation.

"If the contract with either health system went south, it could put each pathology company into serious financial jeopardy," he noted. "It would require major changes in how we do business.

"Our pathologists work in the hospitals because we believe pathologists need to be part of the healthcare team to support the surgeons, oncologists, and other physicians ordering lab tests," stated Adelman. "We pick up the specimens and process them overnight. Then we return the slides in the morning or in the afternoon, depending on when they get to us.

"But the problem with this model is that serving one large health system can be a danger for a pathology group, as we learned a few years ago," recalled Adelman. "At that time, **CHI Franciscan Health** put out an RFP for lab work. The final decision came down to PSIP or CellNetix. At that point, if PSIP had lost that contract, it would have reduced its volume by about 75%. Looking into that potential financial abyss was a wake-up call for us.

Meeting Technology's Cost

"In addition to CHI Franciscan Health, we also serve **Evergreen Health**," Adelman said. "CellNetix has a number of smaller health systems and it has the combined **Providence Health & Services** and **Swedish Health Services**, which is a much bigger organization than CHI Franciscan.

"The third reason for the merger is the need to invest in technology," Adelman explained. "In the past few years, CellNetix invested heavily in advanced technology systems, including end-to-end bar coding and automated processing systems within its laboratory and organization.

"Here at PSIP, we need to retool our technology, and that would include a new LIS," he said. "For new technology, we felt that an investment today of several million dollars might not make sense given the current reimbursement environment and what we can expect in reimbursement in the coming years as a result of the PAMA implementation.

"An equally significant factor for PSIP is that our core lab performs tests on instruments that are up to 30 years old," noted Adelman. "To change this situation would require a substantial capital investment. Meanwhile, the CellNetix core lab has much newer technology that our pathologists and patients can immediately access.

Positioning for Success

"From a capital investment perspective, this is one more reason why a merger between PSIP and CellNetix makes sense, given that they have excess capacity and together we have a larger footprint," said Adelman. "Not only are we better positioned to make the changes we need to make, but we can gain efficiencies."

In conclusion, Adelman explained that the pathology business has long been one that requires continuous strategic thinking. "These are challenging times," he said. "But there are always challenging times in laboratory medicine. And I say that as someone who has been in this business for almost 40 years now. Every day, you have to be able to adapt to the changing environment. With each change, you just have to fight through it." TDR

—Joseph Burns

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Three Reasons Triggered Merger Talks in Seattle

SHOULD THE PROPOSED MERGER between two Seattle-based pathology groups take place, it will be one more example of how consolidation continues to reshape the anatomic pathology profession.

One of the oldest pathology groups in Washington State, Puget Sound Institute of Pathology (PSIP) has provided pathology services for more than 50 years in the Pacific Northwest. Its 17 community-based pathologists in 11 hospitals and health systems in Washington handle 70,000 surgical cases and more than 50,000 PAP and HPV cases annually.

CellNetix has 50 community-based pathologists in hospitals and clinics, mostly in Washington. It also has pathologists in hospitals in Alaska, Idaho, and Oregon. Its pathologists process more than 130,000 surgical cases and more than 150,000 PAP smears annually. The lab company also has small local labs in Everett, Olympia, Spokane, Wash., and in Palmer, Alaska. Like PSIP, its core lab is in Seattle.

The two pathology groups cite three primary reasons why a merger is a smart financial and clinical move:

One: The need to invest in new diagnostic technology in the technical laboratory while using increased specimen volume to cut costs.

Two: The need to provide physicians, hospitals/health systems, and health insurers with broader geographic reach that includes expanded patient access to sophisticated anatomic pathology services.

Three: The need to position the regional pathology supergroup to deal with the expected reductions in payment for pathology services as a result of PAMA, as well as to be ready to deal with how pathology professional reimbursement will change because of implementation of MACRA, with its new MIPS and APM physician-payment systems.

Lab Market Update

Theranos Lays Off More Staff, Voids More Lab Test Results

Once again, a stream of bad news about problems puts beleaguered lab firm in the national headlines

ONCE AGAIN, the controversial lab testing company, **Theranos, Inc.**, found itself the subject of negative news stories. In recent weeks, *The Wall Street Journal* reported that the beleaguered lab testing company in Palo Alto, Calif., laid off 155 staffers, voided more laboratory test results, and cut ties with its high-profile lawyer.

This round of bad news followed earlier stories reporting that some big investors in Theranos may not recoup the funds they put into the company and that patients were not told for months that their lab test results were unreliable.

Last week, Christopher Weaver reported for *The Wall Street Journal* that the company was paying so much in legal fees to defend itself that it was laying off 155 employees on Jan. 6. The brings to 495 the number of positions Theranos had eliminated since October.

"Theranos faces steep legal and other costs amid challenges from regulators, lawsuits by shareholders, and criminal and civil federal probes," Weaver reported.

Posted on the company's website on Friday, Jan. 6, under the headline, "Company Re-Engineers Operations," was this statement: "Theranos Inc. announced further re-engineering of the company's operations as it works towards commercialization of the miniLab testing platform and its related technologies. In the streamlined organization, teams have been aligned to meet product development, regulatory, and commercial milestones." The company had what it called a "core team" of 220 professionals to execute its business plans. The journal stated that the 220 number was about one quarter of the number of employees it had in August.

The miniLab is designed to process and analyze small samples of blood in a portable device, the company said. "Think of it as being a huge diagnostics lab that has been condensed down to the size of a microwave," Theranos said. In August, at the **American Association of Clinical Chemistry** annual meeting, Theranos CEO Elizabeth Holmes unveiled the miniLab and discussed how it operated. *(See TDR, August 15, 2016.)*

More Patient Results Voided

The journal also reported that Theranos had notified an additional group of patients in late December that it had voided their test results. "The company sent out newly corrected results saying some tests done in 2015 and 2016 for hemoglobin A1c, a protein doctors measure to help diagnose diabetes, shouldn't be relied upon, according to copies of the corrected reports," Weaver wrote.

One of those patients who received a corrected result had a diabetes test result from Theranos that showed she was

becoming diabetic. That patient is a plaintiff in a legal action that alleges the company misled patients.

Another one of those patients who got a corrected result was journal reporter John Carreyrou. He had blood drawn in April 2015, also for a Theranos diabetes test. The doctor who ordered the test told him last week that Theranos had voided the result.

Addressing Shortcomings

In a statement to the journal, Theranos said, it was "absolutely committed to assessing and addressing negative patient impact that may have resulted from any shortcomings at the [Theranos clinical] labs." The lab company also said it would continue to review and void blood tests as appropriate until "we have taken all necessary remedial action."

In November, the journal reported that Theranos' chief outside counsel, David Boies, and his law firm, **Boies, Schiller & Flexner LLP**, were no longer working for Theranos. The split came after Boies and Theranos disagreed about the strategy to be used for responding to government investigations of Theranos, Carreyrou wrote.

The lab company is the subject of criminal and civil investigations by the U.S. attorney's office in San Francisco and by the **Securities and Exchange Commission**. The investigations center on whether the company misled investors and regulators about its technology and operations, the journal reported, adding that Theranos said it is cooperating.

Carreyrou reported that the nature of the disagreement with Boies and his law firm was not clear. He wrote that the lab company's general counsel, Heather King, who had previously been a partner at Boies Schiller, left Theranos in early September. At that time, she returned to Boies Schiller.

"People familiar with the matter said Ms. King left Theranos after she and Mr. Boies disagreed with Ms. Holmes about Theranos' legal strategy," Carreyrou reported.

In late November, Carreyrou and Weaver wrote that Theranos has gotten funding from private investors, including large investments from families and individuals, such as Rupert Murdoch, the executive chairman of **News Corp** and **21st Century Fox**, and Riley Bechtel, chairman of the construction company **Bechtel Group**. These investors might see their investments "wiped out by the blood-testing company's regulatory and technological troubles," they wrote.

Several large investments from families and individuals helped infuse Theranos with $632 million in its latest funding round, which stretched from 2014 to 2015, according to those familiar with the matter and documents filed by Theranos in Arizona and Delaware, the journal reported.

Patients Get Bad News

In late October, Weaver detailed how some patients' received dubious test results. "Theranos failed to maintain basic safeguards to ensure consistent results, according to regulators, independent lab directors, and quality-control experts," he wrote.

"A review of regulatory records and interviews with patients shows the Palo Alto, Calif., company didn't just burn investors who bought into its promise to revolutionize the world of blood testing. It also left a trail of agonized patients who had been drawn to Theranos by its claims of convenience, low cost, and reliability."

In recent months, the journal also revealed the name of one whistleblower who had provided internal documents and information about the problems within Theranos. It was Tyler Schultz, grandson of George Schultz, who had been a director at Theranos. The younger Schultz is cooperating with federal investigators conducting multiple probes of Theranos. TDR

—Joseph Burns

In Texas, Questions for UnitedHealth, BeaconLBS

➤Pathologists ask: How does this improve quality? How will we get reimbursed for IHC test claims?

➤➤CEO SUMMARY: As of January 1, 2017, clinical laboratories and pathology groups in Texas will find it more difficult to serve the 500,000 patients enrolled in UnitedHealthcare's fully-insured commercial plans in the Lone Star State. That's because—just as it did in Florida—UnitedHealthcare, with its partners BeaconLBS and Laboratory Corporation of America, is implementing its laboratory benefits management program in Texas as of that date, with claims impact to begin on March 1.

As of Jan. 1, 2017, **UnitedHealthcare** wants physicians and labs in Texas to begin using its laboratory benefits management program that is administered by **BeaconLBS**, a business division of **Laboratory Corporation of America**.

Under the program, physicians treating any of the 500,000 UHC members who are in fully-insured commercial plans through their employers will need to obtain pre-notification or pre-authorization for about 80 clinical lab tests through the BeaconLBS platform. During January and February, use of the BeaconLBS system for lab-test ordering will have no effect on whether UHC will pay the labs that run these tests. Starting, March 1, however, each time physicians do not use the BeaconLBS platform when ordering these most-common tests, UHC will not pay the labs that performed those tests.

Throughout Texas, pathologists are beginning to learn more about this new UnitedHealthcare requirement. They are raising many questions about how the BeaconLBS program will work and what effect it will have on clinical laboratories and referring clinicians.

The first question THE DARK REPORT hears from pathologists in Texas is: "What is UnitedHealthcare's aim in adopting this program?" That question is generally followed by: "How will pathologists get paid for immunohistochemistry tests when referring physicians don't order IHC?"

➤What's the Goal?

Most pathologists in Texas remain unaware of the full details of UHC's laboratory benefit management program. But those pathologists who followed its use in Florida are concerned about how its implementation in Texas will disrupt long-standing physician and patient relationships, not to mention the negative financial impact their colleagues in Florida have reported.

"Did UHC set up this program to save money or shift costs to pathologists?" asked a pathologist from a large group in the Houston metro. "UnitedHealthcare has 80 tests that must go through the BeaconLBS decision-support system.

"It sure looks to me like the way they developed this list of 80 tests is by taking the top 80 payouts by CPT code," he said.

"By that I mean UnitedHealthcare set up this program to save money on the most common tests. It seems to me the only reason they are doing this is because saving money is their ultimate goal. If UHC wants to improve quality, it won't achieve that by selecting the top 80 tests by payout by CPT code.

Cost Shifting to Labs?

"These are high-volume tests," he added. "That's what makes me think UHC's laboratory benefit management program is about shifting costs to labs and physicians. UHC simply asked, 'What are the top CPT codes that we pay out?' Once they identified those top tests by volume, that became their list."

Another pathologist from San Antonio who agreed to speak off the record to THE DARK REPORT raised an important question: How does UHC and BeaconLBS intend to handle IHC claims from pathology labs? "Included on the list is Immunohistochemistry, which is CPT code 88342," she stated. "But pathologists order this test when working up a biopsy case. A referring clinician never orders immunohistochemistry. If the clinician doesn't order the test, and pathologists are not allowed to do the pre-notification through the BeaconLBS system, then how does the pre-notification get done?

"I understand that, at one of the meetings conducted by UHC, labs were told that they cannot do the pre-notification and so all we can conclude is that we'll never get paid for immunohistochemistry," she noted. "That's a question we want the **Texas Society of Pathologists** (TSP) to get answered the next time it meets with officials from BeaconLBS and UHC."

THE DARK REPORT has learned that, in November, some members of TSP had a 30-minute conference call with representatives of BeaconLBS, UnitedHealthcare, and LabCorp. The call included a demonstration of the BeaconLBS system. At least two pathologists who monitored the call agreed they appreciated the opportunity to learn about the system. But the three companies' representatives presented too much information in a short time.

"It was like drinking from a firehose," noted one pathologist who listened to the conference call. "We didn't have time to formulate questions or even to digest what we heard.

"From what little we could tell from the demonstration, the BeaconLBS system does not look ready to be rolled out," he commented. "On January 1, use of the BeaconLBS system will be voluntary for the first two months. Then, on March 1, it will be mandatory. But it looks like the implementation will be rushed.

"In addition, there's not enough time for pathologists or referring clinicians to test the system so that we'll be ready on March 1," he said. "And, if it's a sloppy rollout, that tells you that they are not interested in quality of care.

"For example, the BeaconLBS people said they have interfaces in place with seven electronic health record systems," continued this pathologist. "And, they admitted that a doctor who does not use one of those seven EHR products will have to use the freestanding BeaconLBS portal.

Time-Consuming For Docs

"Using the BeaconLBS portal is a huge problem because the system is ponderous and time-consuming for a physician to use to obtain pre-notification or pre-authorization when ordering lab tests," he explained. "When it doesn't integrate, the referring clinician has to use two systems to order each test, his or her own EHR and the BeaconLBS portal.

"Plus, the BeaconLBS system has been running in Florida for more than a year, which raises the question of why is it that UHC and BeaconLBS have interfaces with only seven EMRs? That's a very small number," he added. "What are they waiting for? They should just integrate with all

of the most common EHRs rather than make it difficult for most physicians to use the system.

"The Beacon representative responsible for EHR integration was on the conference call and said, 'We're committed to integrating with all of the most widely used EHRs. You pathologists just have to let us know which ones your clients use and which ones you want and we'll connect those EHRs for you,'" noted the pathologist.

"To me, this is balderdash! I don't see that as our job! UHC should know enough about its market and its contracted physicians to know which EHRs Texas clinicians use," emphasized the pathologist.

Attempt To Cut Costs

"From all that I've learned so far, it's clear what they're trying to do," he said. "The design of this program tells me that they are not trying to increase quality, and they are not trying to lower the cost of care. They're trying to cut their expenses and steer referrals to the lowest-cost lab within their provider network."

The Houston pathologist agreed with this assessment. "My pathology laboratory meets every one of their quality mandates to be a lab of choice, but if—according to my existing UHC contract—if my lab's fees are not in the bottom quartile, our lab is excluded," she explained. "This pricing requirement is an independent criteria that they added on. It's a made-up thing.

"In other words, I can make a strong argument that UnitedHealthcare and BeaconLBS created a new, systematic way to deny payments to labs," she continued. "They know that the law requires a laboratory to perform the tests ordered by a physician. So the lab will perform the tests and the physician and patient come out okay, but the laboratory that performed the tests does not get paid by UHC and BeaconLBS because of these other restrictions!" TDR

—By Joseph Burns

Texas 'Clean Claims' Law Might Be Problem for UHC

ONE TEXAS PATHOLOGIST who works with the Texas legislature on laws and regulations that affect clinical laboratories and anatomic pathology groups raised an interesting question: "What effect will the clean claim law in Texas have on how UnitedHealthcare and BeaconLBS handle claims from clinical labs and pathology groups?

"I could meet every one of their quality mandates to be a lab of choice, but if under my existing UHC contract, my fees are not in the bottom quartile, I'm out!," he said. "That's an independent criteria that they added on. It's a made-up thing.

"In other words, they gave themselves a new and systematic way to deny payments, but here in Texas they might have a problem," explained this pathologist. "Texas' clean claim law says that, within a certain period of time, insurance companies have to pay a clean claim—meaning one that has every CMS-required element completed correctly.

"There is no mention in the clean claim law about the authorization or notification number that referring clinicians have to get through the BeaconLBS system," he added. "Nowhere is that part of the definition of a 'clean claim' under Texas law.

The pathologists' society has raised the clean-claim issue with lawyers from the **Texas Medical Association**. A spokesman for the TMA said the association is working with representatives from BeaconLBS.

Meanwhile, THE DARK REPORT made an inquiry about the clean claims law to the **Texas Department of Insurance**. A public information officer wrote the following, "If it's [a] fully-insured [health plan], we would regulate it even if it is employer-sponsored. Clean claims laws would generally apply. We would need to know more about the program to comment further."

Legal Update

NJ Lab Sues to Challenge Payers About Its Out-of-Network Status

MDL sues Independence Blue Cross of Philadelphia and LabCorp over exclusion as network provider

ONE WAY THAT A CLINICAL LAB can fight back against insurers who refuse to pay lab test claims is to sue them. That's exactly what **Medical Diagnostic Laboratories** of Hamilton, N.J. is doing!

Not only has MDL filed lawsuits against two major health insurance companies, but in one lawsuit, it named a national lab company as a co-defendant. In August, MDL filed suit in U.S. District Court for the Western District of Oklahoma against **HCSC**, a managed care company that operates **Blue Cross Blue Shield** plans in Illinois, Montana, New Mexico, Oklahoma, and Texas.

In this lawsuit, MDL said HCSC operated in a heavy-handed, arbitrary, and capricious manner to keep MDL from serving as an in-network laboratory provider in Oklahoma, even though HCSC has approved MDL as an in-network provider for its operations in Illinois and Texas.

Then in November, MDL filed an antitrust lawsuit in U.S. District Court for the Eastern District of Pennsylvania against **Independence Blue Cross of Philadelphia** and **Laboratory Corporation of America**. MDL seeks triple damages for what it claims were strategies by the two defendants to limit competition in Southeastern Pennsylvania by excluding MDL from being an in-network provider for infectious disease testing.

In the lawsuit, MDL cited four counts: violation of the Sherman Act, tortious interference with existing business relations, tortious interference with prospective business relations, and unfair competition. In the lawsuit, MDL seeks an injunction against IBC and LabCorp and punitive and compensatory damages.

Founded in 1997, MDL specializes in infectious disease testing and has 670 employees in its CLIA-certified and CAP-accredited lab in Hamilton. MDL said it has provider agreements with 32 of the nation's 38 Blue Cross Blue Shield plans.

Philly Market Dominance

In the lawsuit, MDL charged that IBC controls 67.5% of the insurance market in Southeastern Pennsylvania, thus making it impossible for labs and other health care providers to be economically viable without in-network status. "Through repeated and ongoing exclusionary and threatening conduct, defendants have violated federal and Pennsylvania law by preventing MDL's ability to retain current, and obtain new, clientele…" the lawsuit said.

The defendants threatened to impose penalties and other sanctions and expel healthcare providers from its network if they referred lab tests to MDL, court documents showed.

In one case, in the summer of 2016, IBC telephoned and wrote to a healthcare

provider, threatening that if the provider continued to use out-of-network providers, including MDL, it would not be paid for its services and would face other penalties too, the suit said.

The purpose of excluding MDL was to allow LabCorp to dominate the laboratory services market in Southeastern Pennsylvania, including the counties of Bucks, Delaware, Lancaster, Lebanon, Montgomery, Northampton, and Philadelphia, the suit said. As a result, MDL said it suffered serious losses of business and profits.

Anticompetitive Agreements

"As alleged herein, defendants entered into anticompetitive agreements with each other by which, through the exercise of IBC's market power in the Southeastern Pennsylvania health insurance market, they restrained trade in the STI specialty testing market…" the lawsuit said.

One interesting aspect of the lawsuit is that it explained the network for lab services that IBC uses today. For example, the lawsuit said, IBC entered into an agreement with LabCorp on July 1, 2014, to make LabCorp its exclusive, national provider of outpatient laboratory testing services.

"When IBC entered into this agreement with LabCorp, it expressly represented that in-network providers of laboratory services would remain in-network," the lawsuit said. "In fact, to this day, IBC's website, in discussing the effect of IBC's arrangement with LabCorp, expressly states that 'all other laboratories' currently in Independence's network will remain in-network providers with the exception of **Quest Diagnostics Incorporated**."

In 2014, THE DARK REPORT reported on the exclusive arrangement that IBC developed with LabCorp and how that arrangement excluded Quest Diagnostics. *(See TDR, June 30, 2014.)*

The lawsuit continued, saying, that the statement that all other labs would remain in-network is false because LabCorp owns all of IBC's in-network laboratories within 200 miles of Philadelphia, the lawsuit said.

Drop In Specimen Volume

In 2014, MDL's specimen volume began to drop and dropped dramatically in 2015 and early 2016, the lawsuit said. The reason for the decline in specimen volume was coercion by IBC and LabCorp against in-network providers to get them to stop using MDL, the lawsuit said.

MDL documented in the lawsuit how it contacted nine healthcare providers that had stopped using its services to inquire about why the providers had done so. In each case, the providers said that they felt threatened if they did not discontinue using MDL.

In making its case, lawyers for MDL explained in the lawsuit that MDL provides reflex antibiotic resistance and susceptibility testing for four specific forms of infection and MDL is the only lab whose antibiotic-susceptibility testing (AST) services are performed for three of those infections at the time the infection is detected. "This allows the physician to prescribe the correct antibiotic and prevent the spread of the infection," the lawsuit said.

Requirements For Testing

LabCorp does not perform such AST testing for these four infections, the suit claimed. LabCorp will perform AST if the physician orders such testing but that means the physician must first get the initial test result or wait until the patient fails treatment based on the antibiotic the physician chooses.

Correctly identifying the pathogen during initial testing ensures that patients are prescribed the most effective and appropriate medications for their conditions, improving patient care and helping to prevent the spread of the infection, the court documents stated. **TDR**

—Joseph Burns

China Invests $9 Billion In Precision Medicine

United States is undisputed leader in use of genomics, but China wants to catch up

CEO SUMMARY: In the 1960s, it was a race to be first in space between the United States and the Soviet Union. This decade, it's a race to be first in genetic and precision medicine between the U.S. and China. To that end, the Chinese government has budgeted $9 billion as an investment to further research and development of genetic technologies and their use in precision medicine. One irony in this situation is that many of China's 20,000 hospitals lack the same expertise and subspecialist capabilities in anatomic pathology and laboratory medicine that are common in the West.

CHINA IS UPPING THE ANTE by a big margin in the race to use genetics to revolutionize how health is improved and disease is treated. In January 2015, President Obama was praised when he announced a $215 million investment in precision medicine.

Meanwhile, the Chinese government has an initiative with similar goals but with a much larger budget: $9 billion!

Ylan Q. Mui reported in *The Washington Post* last week that the Chinese effort is significant. The United States has been the undisputed leader in the use of genomics, she wrote. "But now China is emerging as America's fiercest competitor, and it is sinking billions of dollars into research and is funding promising new companies both at home and abroad," she added.

In her article, Mui quoted Eric Schadt, PhD, Director of the **Icahn Institute for Genomics and Multiscale Biology**, Chair of the Department of Genetics and Genomics Sciences, and the Jean C. and James W. Crystal Professor of Genomics at the **Icahn School of Medicine at Mount Sinai**. "I'm very frustrated at how aggressively China is investing in this space while the U.S. is not moving with the same kind of purpose," Schadt said. "China has established themselves as a really competitive force."

China's $9 billion investment in precision medicine is designed to sequence genes and develop customized new drugs based on that data, Mui reported.

"The U.S. system has more dexterity and agility than the Chinese system," Mui wrote, quoting Denis Simon, Executive Vice Chancellor of **Duke Kunshan University** in China, a partnership of **Duke University** and **Wuhan University**. "But the learning curve in China is very powerful, and the Chinese are moving fast. The question is not if. The question is when."

Public, Private Investments

One part of the Chinese effort involves investments by private companies and the Chinese government into American start-up genomics companies, Mui reported.

Since 2000, China has invested more than $3.6 billion into our health and biotechnology sector, according to the **Rhodium Group**, a consulting firm, she added.

Another part of the Chinese effort involves companies such as **WuXi NextCODE**, a genomic information and precision medicine company with operations in Shanghai, Cambridge, Mass., and Reykjavik, Iceland. In February 2016, WuXi (pronounced woo-she) announced that its Shanghai sequencing lab was accredited by the **College of American Pathologists** and was the first lab in China to be licensed by the State of California. At the time, it was the only sequencing facility in China that was CLIA certified.

Six National Projects

Just last week, Allison Proffitt reported for *BioITWorld* that the **National Heart Centre** of Singapore had chosen WuXi NextCODE to work on its 18-month proof-of-concept precision medicine project for cardiovascular disease. The project is a first step in Singapore's national precision medicine initiative, she wrote. In the project, researchers will conduct whole genome sequencing on cardiovascular patients and on a control group of healthy patients. Although the exact number of patients who will participate in the project has not been released, WuXi NextCODE COO Hannes Smarason expects a few thousand cardiovascular and healthy patients will be involved, Proffitt reported.

For WuXi NextCODE, the Singapore project is its sixth national program, along with others in China, England, Iceland, Ireland, and Qatar, Proffitt wrote. Its platform is capable of handling data from hundreds of thousands of participants.

WuXi NextCODE is a division of **WuXi AppTec**, a company with an estimated net worth of $3.3 billion and 14,000 employees worldwide. Ge Li, PhD, a former laboratory scientist, founded WuXi in 2000. On WuXi's website, Li is quoted as saying, "Our vision is to become the most comprehensive capability and technology platform in the global pharmaceutical and healthcare industry to fulfill the dream of 'every drug can be made and every disease can be treated.'"

Here in the United States, WuXi has invested in **23andMe**, tests medical devices in St. Paul, Minn., develops biologics in Atlanta, and it is opening a biomanufacturing plant in Philadelphia, Mui reported in *The Washington Post*.

At one time, WuXi's largest division was listed on the New York Stock Exchange, but the company is privately owned today, Mui wrote. It may go public again on a Chinese exchange, she added.

For Mui, Smarason described WuXi NextCODE this way: "We're a U.S. company in the U.S., but we're a Chinese company in China. We're local in every market."

Cloud Project Takes Flight

In May 2016, *BioITWorld* reported that WuXi AppTec was partnering with **Huawei**, an information and communications technology company in Shenzhen, China, to launch the China Precision Medicine Cloud to support the Chinese government's precision medicine initiative and to link researchers across China through a secure nationwide network.

For the cloud project, Huawei will contribute its national cloud-computing network, WuXi AppTec provides the sequencing capability, and WuXi NextCODE will organize, mine, and share the data, *BioITWorld* reported.

"WuXi AppTec and WuXi NextCODE solutions already meet many U.S. standards, and have proven their ability on large, collaborative projects," *BioITWorld* wrote. For example, in 2015, **Genomics England** named WuXi NextCODE to be its first clinical interpretation partner in the field of cancer, *BioITWorld* reported. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

December 27 was the 100th birthday of pathologist Jan Steiner, MD, FRCP(C), FCAP, remembered by many long-serving lab executives and clinical pathologists as one of the co-founders, along with James Root, PhD, of **Chi Laboratory Systems** in the late 1980s. This was a time when he was already in his 70s. He worked with Chi and its successor company, **PCS Solutions**, into his 90s. Steiner was always known for his high energy and his dynamic presentations at lab conferences. He is reported to be healthy and happy in retirement in Michigan.

MORE ON: *Dr. Steiner*

Born in Czechoslovakia, Steiner trained in Prague, Liverpool, and Oxford. He survived World War II and found his way to Canada. He was senior pathologist at **Toronto General Hospital** for 20 years. Upon arriving in the United States, Steiner became Director of the **Illinois Comprehensive Cancer Center**, under the aegis of the **National Cancer Institute**. Steiner authored more than 200 scientific papers. In 1982, Steiner became the Medical Director for the U.S. operations of **MDS Health Group**. In 1985, he joined **Chi Systems** of Ann Arbor, Mich. Within a few years, Steiner and Root spun off the lab consulting business of Chi to form Chi Laboratory Systems.

FEDS INDICT DOC IN NJ BDL CASE

Another physician has been indicted in the federal case of fraud and abuse involving the now-defunct **Biodiagnostic Laboratory Services** (BLS) of Parsippany, NJ. Internist Thomas Savino, MD, of Staten Island, NY, faces multiple counts, including conspiracy. He is accused of accepting $25,000 in bribes in exchange for making lab test referrals worth $325,000 to BLS.

TRANSITIONS

• Cynthia Collins will assume duties as CEO of **Human Longevity, Inc.**, of San Diego, allowing founder and current CEO Craig Ventor, PhD, to be Executive Chairman of HLI's Board of Directors. Collins held leadership positions at **GE Healthcare**, **Clarient Diagnostics GenVec**, **Beckman Coulter**, **GenMarkDiagnostics**, **Baxter Healthcare**, and **Abbott Laboratories**.

• **Illumina** named Jonathan Seaton as its new Senior Vice President for Corporate and Business Development.Seaton previously held executive positions at **BD**, **Roche Diagnostics**, **Roche Tissue Diagnostics**, **LS9**, and **Deutsche Bank**.

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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 intriguing findings of a study published in *JAMA* that indicates that being a "second user" of a bed previously used by a patient taking antibiotics may be another risk factor for acquiring *Clostridium difficile*. *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, January 30, 2017.

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