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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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R. Lewis Dark
Founder & Publisher

When Competing Hospitals Come Together

MANY ANATOMIC PATHOLOGY GROUPS that have enjoyed contracts with one or more hospitals for decades now find those relationships challenged or disturbed by the spate of mergers and acquisitions happening with hospitals and health systems. This trend will carry forward for several more years.

At least two distinct forces are encouraging hospitals and health systems to collaborate, merge, or acquire. First, if two important hospitals in a community can come together, it improves their ability to contract for higher prices with private health insurers. Last month, *The New York Times* wrote a story about how the 1994 merger of **Massachusetts General Hospital** and **Brigham and Women's Hospital** to form **Partners HealthCare** resulted in giving "the hospitals enormous market leverage to drive up healthcare costs in the Boston area by demanding high reimbursements from insurers that were unrelated to the quality or complexity of care delivered."

On that same point, last week *The Wall Street Journal* wrote about how such mergers in New York had raised concerns that hospitals involved in these transactions would be able to raise prices without offering any improvement in the quality of care.

The *WSJ* pointed out that "in New York state, at least a dozen hospitals, many of them financially ailing, have become part of larger networks since 2011, according to the state Department of Health. More than a dozen hospitals have new owners or new affiliations in New Jersey during the same period as well." Pathologists should take note of how much merger activity is happening.

The second reason why hospitals that were long-time competitors are collaborating, merging, or acquiring is to counter the narrow networks that payers are developing. A solo hospital in a community is easy for a payer to exclude from a network. But if the community's hospitals are all under one health system, payers are more likely to include them in provider networks.

For community pathology groups, such merger and acquisition activity can represent an opportunity to recast the clinical and business relationship with their hospital or health system administration. This is particularly true if the individual pathology groups involved in a merger decide that they can also work closely together, whether through tighter collaboration while remaining independent or through a merger of their groups. TDR

Ignoring Lab Industry, Theranos Goes Its Way

Unknown to the wider clinical laboratory industry this emerging laboratory test firm has disruptive plans

CEO SUMMARY: With each passing month, Theranos pulls open the curtain a bit more on its business structure and its market growth plans. Its clinical lab tests are now offered in Walgreens pharmacies in Palo Alto, California, and Phoenix, Arizona. Recent news coverage in Fortune and USAToday disclosed that company officials—based on stock sales to date–value the company at $9 billion. That's more than the market value of the shares of Quest Diagnostics or LabCorp.

ONE COMPANY WITH BIG AMBITIONS in the clinical laboratory testing market is **Theranos**, based in Palo Alto, California. It has declared its goal of introducing disruptive technology and a different lab testing business model into clinical practice.

In recent months, Theranos has been the subject of high-profile media stories. Theranos founder Elizabeth Holmes made the cover of *Fortune* in June and her company was the subject of a detailed story in that issue. Then, on July 8, *USA Today* ran its story about Theranos.

The elevator pitch for Theranos has four basic elements: It intends to revolutionize (and disrupt) the existing process of clinical laboratory testing because it can use (1) a finger-stick to collect (2) a micro-quantity of specimen from which it can perform hundreds of lab tests. It can (3) produce lab test results in four hours and (4) will charge only 50% of Medicare Part B prices.

In September, Theranos and Walgreens, the nation's largest pharmacy chain, announced that the companies agreed to establish Theranos lab testing services in the more than 8,200 **Walgreens** pharmacies nationwide. That same week, *The Wall Street Journal* published an article about Theranos that discussed the company's plans in positive terms. *(See TDR, September 30, 2013.)*

Currently, there are two Walgreens pharmacies in Palo Alto, California, where patients can obtain Theranos lab tests. In Arizona, Theranos shows 29 Walgreens pharmacies that offer its lab tests and, at this time, all these locations are in the Phoenix metro area.

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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Publication of the *Fortune* and *USA Today* stories about Theranos came in the weeks before the **American Association of Clinical Chemistry's** annual conference in Chicago. For this reason, many lab scientists and vendors at the conference were asking questions about Theranos.

Secretive Company

Because Theranos has a reputation as being secretive (and litigious), little is known about the company, outside of the carefully-orchestrated news stories that the company allows to be printed. Former employees, for example, are not allowed to identify their former employer on their resumes.

At the center of the media coverage is Elizabeth Holmes, the founder and CEO of Theranos. News accounts describe how she dropped out of Stanford in 2003 at the age of 19 to found the company.

According to *Fortune*, since the company's founding, it has attracted $400 million of venture capital. Its investors say that the company is valued at $9 billion.

Elizabeth Holmes, founder of Theranos, was featured on the cover of the June issue of *Fortune Magazine.*

For comparison, in today's stock market, **Quest Diagnostics Incorporated** (2013 revenue of $7.1 billion) is valued at $8.7 billion. **Laboratory Corporation of America** (2013 revenue of $5.8 billion) is valued at $8.8 billion. Thus, despite its diminutive presence in the clinical testing marketplace today, executives at Theranos are declaring that the company is more valuable than the nation's two multi-billion-dollar lab testing behemoths.

Details discussed in the *Fortune* story will help pathologists and lab managers understand the elements the company says will make it disruptive. These center upon small specimen quantities.

Fortune noted that the company currently has approximately 200 different lab tests that it can perform with its microspecimens. It is regularly validating and adding additional tests to that number.

Moreover, wrote *Fortune*, "The company has performed as many as 70 different tests from a single draw of 25 to 50 microliters collected in a tiny vial the size of an electric fuse, which Holmes has dubbed a 'nanotainer.' Such a volley of tests with conventional techniques would require numerous tubes of blood, each containing 3,000- to 5,000-microliter samples."

The big question that THE DARK REPORT hears from pathologists and lab executives is "what technology Theranos is using to do extensive testing on such small specimens?"

On this point, *Fortune* wrote that, "Precisely how Theranos accomplishes all these amazing feats is a trade secret. Holmes will only say—and this is more than she has ever said before—that her company uses 'the same fundamental chemical methods' as existing labs do. Its advances relate to 'optimizing the chemistry' and 'leveraging software' to permit those conventional methods to work with tiny sample volumes."

Working With Health Systems

It was also disclosed in the *Fortune* story that Theranos was now "working closely... with the aim of deploying its lab services at **UCSF Medical Center** in San Francisco, **Dignity Health's** 17-state hospital group, and **Intermountain Healthcare's** 22-hospital system in Utah and Idaho."

The *Fortune* reporter did note that the laboratory medicine profession has questions and criticisms about what is publicly

known about Theranos. *Fortune* wrote, "The most frequent criticism is that Theranos is using purportedly breakthrough technology to perform tests that are relied on for life-and-death decisions without having first published any validation studies in peer-review journals."

On this point, Richard A. Bender, M.D, "an oncologist who is also a medical affairs consultant for Quest Diagnostics," was quoted by *Fortune* as saying "I don't know what they're measuring, how they're measuring it, and why they think they're measuring it."

No Peer-Reviewed Studies

The rebuttal on this point by Holmes, wrote *Fortune*, was that "peer-review publication of validation studies is both unnecessary and inappropriate" because "her tests employ 'the same fundamental chemical methods' as existing tests."

Holmes went on to note that Theranos was proceeding under the FDA's laboratory-developed test (LDT) exemption. Wrote *Fortune*, "Moreover, Holmes stresses, Theranos is currently seeking FDA clearance for every one of its tests, even though it's under no legal obligation to do so. (She has submitted many hundreds of pages of validation data in this effort, and has shown much of that data to *Fortune*.) Theranos may, in fact, be the only lab to have ever sought FDA clearance for LDTs." Some pathologists and Ph.D.s will certainly challenge the truth of that last sentence, as multiple companies have obtained FDA clearance for their LDTs.

Another fact came out of the *Fortune* story which may help lab professionals understand how Theranos gained access to the human specimens that would be useful in validating the performance and analytical accuracy of its proprietary diagnostic technology. "...since 2005 Theranos has been doing work for major pharmaceutical companies, including **Pfizer** and **GlaxoSmithKline**, that are conducting clinical drug trials. Early on it was a way for the company, working under confidentiality agreements, to stealthily refine its technology while earning revenue needed to build out infrastructure. Theranos would test drug-trial subjects three times a week—which wouldn't have been feasible using venipuncture—and catch adverse drug effects quickly, before they became dangerous."

Theranos to Hire 500 In Phoenix Expansion

LAST MONTH, NEWSPAPERS IN PHOENIX reported that Theranos had signed a lease for a major office facility in the city.

The company will occupy 20,000 square feet in the SkySong development. This is the **The Arizona State University Scottsdale Innovation Center**.

News accounts said that Theranos plans to hire 500 people to work in this office. It currently has 100 employees in Arizona.

Growing Patent Portfolio

Another point of interest for *in vitro* diagnostics companies is the patent portfolio that Theranos is building. According to *Fortune*, Holmes is a co-inventor on 82 U.S. and 189 foreign patent applications. Of these, 18 in the U.S. and 66 abroad have been granted. Theranos has also filed 186 patents worldwide which don't list Holmes as an inventor and 18 of those have been granted to date.

Another interesting development is that, in September 2013, *The Wall Street Journal* reported that Theranos had gone through $100 million in capital during its 10-year life. Now, 10 months later, *Fortune* is reporting that the company has $400 million in capital investment. This addional $300 million in capital would imply that Theranos has a substantial war chest available to use in its drive to disrupt and transform the clinical laboratory testing marketplace as it exists today. TDR

My Visit to Walgreens For Theranos Lab Tests

➤Secretive lab test company is getting profiled by national the press, but is it delivering to patients?

➤➤CEO SUMMARY: One of the biggest unknowns in the lab testing industry today is Theranos, the lab testing company based in Palo Alto, California. It says its proprietary technology is poised to transform the lab testing experience for patients and physicians. It says it can perform hundreds of lab tests, using a finger stick collection with a micro-specimen and return results in four hours. Here is the actual experience of your DARK REPORT editor, who had Theranos perform lab tests for him and his physician.

By Robert L. Michel

MANY CLINICAL LAB EXECUTIVES and pathologists are asking tough questions about **Theranos**, the company in Palo Alto, California, that boasts it can provide medical laboratory tests to patients at 50¢ on the Medicare Part B dollar—and do it without a venipuncture and return results in four hours!

Since it made its media debut last September, Theranos has enjoyed sweetheart business profiles in such nationally-prominent media outlets as *The Wall Street Journal*, *Wired Magazine*, *USA Today*, and *Fortune*. However, clinical laboratory scientists of all disciplines and fields have commented that these stories about Theranos are one-dimensional.

➤Unanswered Questions

To date, this high-profile media coverage has yet to address the topics of highest interest to the laboratory medicine profession: What is the nature of the diagnostic technology in use at Theranos? What are the specifics about how the company validated the accuracy and reproducibility of its proprietary diagnostic technology for use in clinical settings? What is its strategy to meet federal and state laws and regulatory requirements for the lab testing activities it plans to deliver via 8,200 Walgreens pharmacies and other settings?

Given this vacuum of knowledge about Theranos and its current clinical lab testing operations, this reporter decided to do something that no reporter from any of the major media sources writing detailed profiles about Theranos is believed to have yet done: walk into a Walgreens anonymously, have some medical laboratory tests performed, and compare the actual service delivered to this patient today versus the benefits the company has emphasized in its media coverage.

To provide context to this real-world experience, when interviewed by various media outlets, Theranos emphasizes that patients enjoy the following benefits when using the company's medical laboratory testing service:

- No need for a venipuncture. A simple finger stick is all that is required.

- No need for 3 to 4 vacutainers of specimen. A micro-sample is adequate.
- Theranos' proprietary test technology returns answers in four hours.
- Theranos says it can perform "hundreds of laboratory tests."
- Theranos is charging just 50% of the Medicare Part B lab test fees for the tests it performs.

Lab Testing By Theranos

It was a sunny day in March when I walked into one of the two Walgreens pharmacies in Palo Alto, California, that offer the Theranos medical laboratory testing service. What follows is my experience, taken step-by-step.

Upon walking into the pharmacy, located on University Avenue in Palo Alto, I spotted the Theranos sign in the rear, next to the pharmacy counter. There were three windows. Two windows were labeled "Prescription Drop Off + Pick Up." The window at right was labeled "Theranos Check-in." To the right of this service counter was a small waiting room for Theranos patients and behind that was a private room where the Theranos specimen collection is done.

I presented at the Theranos check-in window. I had a Theranos laboratory requisition signed by a physician. On this requisition were six tests. An individual who identified himself as a Walgreens pharmacist assistant greeted me.

Lab Test Registration

I was identified as a "walk-in patient" because my information was not entered into the Theranos system before my arrival. The assistant took the paper lab test requisition and began to enter data into a computer. I was handed a clipboard with the standard "fill out this information" request for routine disclosures, including HIPAA. I did this in two minutes as I stood in front of the window (while the pharmacy assistant continued to enter my information).

The assistant then left the window and a moment later the pharmacist walked up and continued my lab test transaction. She worked with the computer and printed out several documents. She informed me that my specimen collection would need to be done with a regular venipuncture (not a finger stick, as Theranos represents). I agreed to the venipuncture process.

Next, my total charges were identified and I made payment with cash. I was handed a receipt and told to wait in the reception room.

It should be noted that, at no time during this transaction, did any Walgreens or Theranos employee call my attention to the fact that Theranos would not be performing 100% of the lab tests ordered by my physician. Thus, I went to the next step unaware of this fact. It would mean that, as a patient, I would need to go to a second laboratory to have that lab perform the tests that Theranos did not.

The time from presenting at the Theranos Check-in window until completing that stage in the transaction took 11 minutes.

Standard Venipuncture

Within a minute of my entering the waiting room, a phlebotomist opened the door and invited me into the specimen collection room. After doing a positive patient identification, the phlebotomist notified me that my collection would require a normal venipuncture and asked if that was acceptable to me. I said yes.

Per California state law, this individual was certified as a phlebotomist. She was professional and competent in all respects. As part of the collection, I asked which vacutainers were associated with which tests. The phlebotomist answered that she did not know that information, because she does not see (on her computer order screen) which tests were to be performed. Rather, she only sees what collection supplies Theranos has determined are necessary to fulfill my lab test order.

What is interesting about this aspect of the Theranos specimen collection protocol is that the phlebotomist would not be able to confirm, for example, some basic and relevant facts that could affect the accuracy of the lab test results. One example is whether the patient had been fasting if a cholesterol test was being performed.

Results Ready 'In Hours'

The venipuncture went without incident. (Phlebotomists always tell me that I have good veins!) I asked when my results would be ready. I was told that a Theranos courier would pick up the specimens and take them to the Theranos laboratory in Palo Alto (which is a CLIA-licensed laboratory). She said the results would be ready "in a few hours" and would be transmitted to my physician. Theranos would also notify me when my lab test results were ready to view on its website.

Based on my experience as a walk-up patient, here is how the Walgreens and Theranos encounter can be summarized relative to the key benefits the company says it delivers:

- Venipuncture required (Theranos was unable to collect with a finger stick).
- 3 to 4 regular vacutainers collected (Theranos was unable use its micro-container collection device).
- Unable to return lab test results in 4 hours. (Collection was done on a Thursday afternoon. Lab test results were transmitted to physician and to me on the following Tuesday).
- Theranos was unable to perform all six lab tests ordered by my physician. That required me to visit two labs (and endure two separate venipunctures) in order to complete the full set of lab tests ordered by my physician.
- Theranos did charge 50% of the Medicare Part B lab test fees for the tests it performed.

Assume that I was a patient that arrived at the Palo Alto Walgreens pharmacy with expectations that Theranos could perform all the tests my doctor ordered, would only need to prick my finger for a micro-specimen, and would report the lab test results in four hours—all for a price that was half of Medicare Part B prices. How well did Theranos perform? You can judge for yourself.

To my knowledge, this is the first published report by an individual who has visited Theranos as a patient. I know that labs in San Francisco and Phoenix (where Walgreens pharmacies offer Theranos lab testing services) have sent secret shoppers to have lab tests done to assess Theranos as a competitor. THE DARK REPORT invites lab professionals to share with us their own experiences with Theranos. Letters or calls to the editor with comments or insights about Theranos and its business plan are also welcome. TDR

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At This Time, Theranos Operates Like Regular Lab

AT THIS POINT IN ITS OPERATION—and independent of its proprietary technology—Theranos operates as a regular laboratory.

It has patient service centers that are staffed by phlebotomists in certain Walgreens pharmacies in California and Arizona. It must pay to transport specimens to its CLIA lab in Palo Alto. It must also have an electronic lab test reporting capability to interact with ordering physicians and with patients.

This necessary infrastructure is why some pathologists and lab executives wonder how Theranos—with a cost structure comparable to that of other labs—can offer lab tests at 50% below Medicare and cover the full cost of testing.

Do You Have Questions or Information about Theranos?
Contact us in confidence at rmichel@darkreport.com

Lab Market Update

Incyte to Develop New Ways For Pathologists to Add Value

CONSOLIDATION OF PRIVATE PRACTICE PATHOLOGY GROUPS in Washington State has been ongoing. Because of their acquisitions, **CellNetix** and **Incyte Diagnostics** are now the state's two largest pathology groups.

The next challenge for these two pathology super-groups will be developing new ways to add value to a healthcare system moving away from fee-for-service reimbursement and to integrated clinical care.

One such strategy is about to unfold at Incyte. Last month the Spokane-based group acquired **Accupath Laboratory Services, Inc.**, of Seattle. Former owner Robert R. Hasselbrack, M.D., after 45 years of service, was considering retirement.

But instead of retiring, Hasselbrack will take on a new role at Incyte, one that may be unique in the pathology profession. "Hasselbrack will focus on developing and implementing new ways for pathologists to serve the needs of hospitals, health systems, and accountable care organizations delivering population health under a reformed health care system," stated Tom Rehwald, CFO of Incyte Diagnostics.

"Incyte Diagnostics has long been interested in the development of a robust community healthcare outreach program which emphasizes disease prevention, wellness, and population health," said Incyte's President Christopher Montague, M.D. "In his new role, Dr. Hasselbrack will work in marketing and product development."

"We are looking to transform pathology into the future and Dr. Hasselbrack has some unique ideas for us, based on his background as a former family physician and emergency room physician," stated Rehwald. "His background as a treating physician gives him a hands-on perspective that will help us as we develop what we call next-generation pathology services.

"Healthcare reform has created a strong need for providers to focus on preventive medicine," he said. "Traditionally, that's not a role that clinical laboratories or anatomic pathology groups have served. To position ourselves in this new marketplace, we will need to have a role in delivering services designed to serve patients at every point along the continuum of care."

To the Forefront of Care

"Typically, diagnostics drive treatment," noted Rehwald. "Our goal is to position pathologists at the forefront of the continuum of care. That's the role Dr. Hasselbrack can fill for us. He has the concepts and the ideas on how to get clinical and anatomic pathology services to fit in this new healthcare environment. We want to formulate his ideas into programs that we can take out to market.

"The first step will be to determine what ACOs want from clinical pathologists and how comprehensive those offerings need to be," concluded Rehwald. "With that understanding, we can develop pathology services that help the physicians improve patient outcomes in a more cost-effective manner. If we can do that well, then we will succeed and so will our client ACOs." TDR

—Joseph Burns

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***CEO SUMMARY**: To meet the financial challenges of healthcare today, clinical labs and pathology groups can follow the five classic lab rules of success. However, as noted by Stan Schofield, CEO of NorDx Laboratories in Scarborough, Maine, the "old school" methods need to be replaced by "new school" strategies. In this conclusion to a two-part series, Schofield discusses how labs can go new school when following the last two rules, which are "Get Paid" and "Reduce Expenses."*

New ways to implement the old-school rules of get paid and cut costs

NorDx CEO Shares Five Rules Critical to Every Lab's Success

Second of two parts

IT'S A CHALLENGING FINANCIAL ENVIRONMENT for clinical labs today. One factor is healthcare's rapid transformation toward integrated clinical care. Another factor is reduced payment for lab tests when government and private payers cut reimbursement.

Yet one lab CEO says the five classic rules for clinical and financial success still work. To use these rules successfully today, however, labs must apply them differently.

For Stan Schofield, President of **NorDx Laboratories** in Scarborough, Maine, one way to apply the five classic rules for lab success is compare "old school" versus "new school" methods.

Schofield shared his perspectives on these rules at the *Executive War College* in New Orleans in April. *(See part one of this two-part series, TDR, July 21, 2014.)*

"Old school versus new school is a great way to understand why these five classic rules are effective today, but only if followed in new and different ways than we did in the past," observed Schofield. Along with his duties as NorDx President, he is also Senior Vice President of **MaineHealth** and Co-Founder and Managing Principal of **The Compass Group**.

Schofield's lab represents a good example of a regional consolidated laboratory organization within a large health system. NorDx provides clinical diagnostics services to hospitals, physicians, other laboratories, and managed care providers throughout New England. NorDx's parent is MaineHealth, the largest health system in the state.

Schofield's participation with The Compass Group has given him useful perspectives on how other regional lab organizations respond to current trends in healthcare. The Compass Group is an organization of leaders from 24 large integrated delivery systems.

As part of his presentation, Schofield identified these five rules for lab success:

1. Add clients
2. Keep clients
3. Create revenue opportunities
4. Get paid
5. Reduce expenses.

In part one of this series, Schofield addressed the first three rules. In this second and final installment, he outlined the steps labs should take to follow the last two rules.

RULE 4 | Get Paid

Certainly all pathologists and lab managers understand the importance of following this rule. In the old school world, it was much simpler for laboratories to submit claims and get full payment. Today, however, the old school methods are no longer as effective as they once were, Schofield said.

"In the old school approach, if your lab had its own billing operation then you didn't have to work with your parent hospital," Schofield said. "The lab's in-house billing operation allowed managers to temper collection efforts as needed.

"For example, to avoid irritating an influential physician-client, the billing and collections department could soften collection efforts at times when this physician ran up large balances," he noted. "Such flexibility could avoid making this client unhappy, or sad, or mad."

Yet, the focus on medical necessity began to change lab collection practices. "This was the time when payers began to assess medical necessity," explained Schofield. "Payers would refuse to pay for some lab tests if they determined the tests were not needed.

"Suddenly, the lab was on the hook for the cost of those tests," he stated. "This was true even if the patient or the physician or both were not following prior authorization rules.

"Once financial risk was shifted to labs, a lab could no longer let large balances accumulate for any clients," he said. "At NorDx, we had to increase our collection efforts. As we did, we brought our collections under control.

"But that was then," continued Schofield. "Today, the money is going away as payers cut reimbursement for lab tests and implement restrictive coverage rules for certain lab tests.

"This is why the new school approach to rule 4: get paid requires labs to beef up billing operations," he said. "Every lab needs a billing staff that has top-ranked coding expertise and collection abilities.

"Labs have to fight for what's owed to them today," advised Schofield. "We no longer have the luxury to let anyone—patients, physicians, or payers—fail to pay for the lab testing services you rendered."

Slow Payment for Claims

Schofield next addressed slow payment for claims. "It is common for all providers to pay slowly, particularly long-term care (LTC) facilities because they have no money," he said.

"Many LTC facilities are struggling financially," added Schofield. "Industry experts say this sector is in crisis and that between 20% and 30% of the LTC facilities could collapse due to financial problems.

"If they do shut down, good luck to labs that are owed money," he said. "On the financial hierarchy at every long-term care facility I know, the lab is just below the vendor who cleans the parking lot.

"These facilities pay their doctors, nurses, and pharmacists," noted Schofield. "They pay their utility bills and—after they pay everything else—then they will pay the lab, but only if some money remains.

"That's why this rule is so important," he added. "Revenue cycle management is a phrase everyone uses to describe the new school method of following an old-school rule: get paid.

"So, how do labs effectively implement revenue cycle management?" asked Schofield. "The new school answer to get paid is that labs must have two elements in place.

"First, your lab needs the right expertise in the billing department," he said. "It is no longer acceptable to have someone who knows how to use QuickBooks running the financial operation in your organization. You need an experienced financial manager who understands how revenue cycle management works.

"Second, your lab needs to know its data and carefully manage that data," continued Schofield. "This requires information systems to collect, store, extract, and report data on billing. These systems are absolutely critical to your lab's success.

"Having access to extensive data on every aspect of your billing and collections efforts in real time equips you with what is called business intelligence," he stated. "This helps your billing team know which insurers are paying you and the denial rate for every payer. Also, this data tells the billing team what it can and should collect for each group of patients.

"To do this well, your billing department needs data extraction tools," explained Schofield. "This aspect of revenue cycle management is difficult and it's confusing.

"But it is a great opportunity for labs to collect and view all the data they need to manage every aspect of their operations," he noted. "When you have the right data, the right systems, and the right people running these systems, it gives you the capability to manage every aspect of your business more effectively.

Answers To Right Questions

"Having the right information systems allows you to answer questions every lab needs to answer," continued Schofield. "These questions are:

- How many tests did you run today, this week, this month, quarter, or year?
- What did it cost to run those tests?
- How do those numbers compare to previous months or quarters or years?
- How do those numbers for your lab compare with those of other labs?"

Schofield next addressed revenue cycle management as it pertains to payers. "The new school approach to getting paid requires your billing team to identify how many of your lab test claims going to insurance companies are being denied," he said. "Denials are how insurers make money.

To Manage Test Utilization, Maine Lab Adopts Different Methods, Including a Test Formulary

"PATHOLOGISTS AND CLINICAL lab managers need to be involved in test utilization management in hospitals, health systems, and accountable care organizations today," advised Stan Schofield, President of NorDx Laboratories in Scarborough, Maine.

"In today's new school environment, lab management is all about cost control," he said. "That means test utilization has taken on new importance. Labs must help clinicians use the right test for every patient.

"Consider the role of accountable care organizations," noted Schofield. "ACOs have value oversight committees and pathologists and lab managers need to be members of these committees.

"At NorDx, we present our test utilization projects to these committees," he said. "We don't wait for them to call us. This is the opportunity pathologists have been waiting for: to explain to physicians which tests to order for which patients.

"Our approach is to emphasize test utilization management," observed Schofield. "Computerized test ordering is one of the most powerful tools available to a lab. But to optimize this, the ordering sets must be changed. For example, tests that are not clinically viable must be eliminated.

"Another new school strategy is to use a lab formulary, particularly for the most expensive tests," he continued. "Some reference tests cost $3,000 or $4,000 each. Devote resources to where the big bucks are.

"Ask yourself this question: How many CBCs or cholesterol tests do you have to eliminate to make up for one $3,000 genetic referral test?" he said "With a lab test formulary and ordering screens, labs can manage utilization effectively.

"The single biggest way to save money in a hospital or a health system is with a comprehensive blood management program," advised Schofield. "When we installed such a program, we saved between 40% and 45% in blood utilization at just one of our hospitals. That amounted to several million dollars per year."

"If you got 50 lab bills from any lab," he stated, "you would find that ten of them—meaning 20%—would be denied simply because someone at an insurance company pushed the denial button to see if anyone was paying attention! The denial rate is high for every laboratory.

"Once denial rates get to a certain level, your lab must take decisive action," emphasized Schofield. "Every unpaid claim must be managed because—with all the new coding for molecular and genetic tests—no lab can afford to go for six months or more with unpaid bills or with billing disputes. Should that happen, your lab will probably not win many of these decisions.

"This is why, in the new school mode, every lab needs detailed information on billing and collections in real time," he observed. "The real time aspect is the key, because the billing team needs to manage these issues immediately, not weeks later.

"A related problem is bad debt," Schofield said. "As one consequence of the Affordable Care Act, hospitals, health systems, and laboratories are now serving more patients than before. However, many of these new patients have high-deductible health plans.

"In the new school approach with rule 4: get paid, this is why laboratories must closely monitor their bad debt," he commented. "In the past 14 months, our bad debt has doubled and that has probably happened at many other labs across the country."

Schofield's Rule 4 and Rule 5 For Laboratory Success

In his presentation at the *Executive War College* in April, Stan Schofield, CEO of NorDx Laboratories, presented his five classic rules of the laboratory business. He described the "old school" approaches, then discussed how labs should pursue "new school" strategies to meet today's healthcare challenges. Here are the last two rules:

Rule 4 | Get Paid

OLD SCHOOL

- Independent lab billing operation—if possible
- Tempered collection efforts to keep doctors happy
- Address medical necessity

NEW SCHOOL

- Billing staff is skilled in coding and collections
- Labs must fight for what is owed
- Revenue cycle management
- Use of data extraction tools
- Fast response to greater number of denials
- Attack sources of increasing bad debt

Rule 5 | Reduce Expenses

OLD SCHOOL

- Cut staff
- Freeze travel
- Freeze hiring
- Freeze capital

NEW SCHOOL

- Reduce expenses
- Monitor sophisticated metrics daily
- Have flexible staffing at every opportunity
- Use buying groups such as Compass Group
- Do direct contracting with diagnostic companies

RULE 5 | Reduce Expenses

Cutting costs is the fifth rule. "Old school methods for reducing expenses were to cut full time staff, freeze travel, and freeze capital," recalled Schofield. "Each of us has done these things in our labs.

"Today, the new school approach is to use detailed metrics to manage costs," he said. "NorDx has metrics to identify trends such as test volume and patient volume. We know how well the hospital is doing with bed days and emergency room visits. We also know the effect on test volume if the hospital closed a clinic, a surgeon moved out of town, or a physician group was acquired by a rival hospital.

"Managers at NorDx have daily numbers, along with weekly, monthly, and quarterly reports on the number of ED draws, critical calls, high-risk incidents, lost specimens, and outpatient draws," noted Schofield. "Each is an operational metric that we monitor.

"We need this data at NorDx because we operate 10 lab facilities and some of them are 140 miles apart," he said. "It is essential for our managers to watch these numbers to know what's happening at every lab site. Access to real-time metrics is the only way to watch trends and intervene in a timely fashion.

"Our daily metrics are detailed and allow us to develop flexible staffing schedules," said Schofield. "It gives our managers the flexibility to use lab staff where they can contribute the greatest value.

"Because of standardization and cross training, we have a 'plug and play' capability," he noted. "With four or five facilities within 20 or 30 miles, we are able to staff these lab facilities almost as if they were a single central lab. That is an excellent way to reduce overtime and cut staff costs in a staff-friendly manner.

"Another new school strategy to reduce expenses is to be smarter in using buying groups," said Schofield. "For example, The Compass Group is a 503(c)(6) trade federa-

tion. Our members are the laboratory corporations of 24 healthcare systems.

Through The Compass Group, NorDx can contract directly with diagnostic companies for new, differentiating technologies," he explained. "By doing so we bypass the group purchasing organizations.

"The reason we do that is that GPOs will take 3% to 5% for administrative fees right off the top, and the lab will never get any benefit from that expense," said Schofield. "Conversely, The Compass Group doesn't have administrative fees because the members contract directly with diagnostic companies.

"Lab test utilization is another opportunity to manage costs—and to avoid fees that IVD manufacturers charge," he said. "In most clinical labs, utilization is dropping and many of us believe it will continue to drop.

"This is a significant trend because many labs have volume contracts with suppliers," continued Schofield. "Should a lab not run the volume it is committed to deliver, it could trigger payments to the vendors. For the first time, the diagnostic companies are enforcing their contracts by checking on the volume commitments and assessing penalties if needed.

Caution About Commitments

"These vendors say, 'You've got until the end of the quarter to pay $15,000,' which is the amount in the contract," he explained. "Of course, labs should not make any commitments into the future. Diagnostic companies hate when I say that. But these are issues to negotiate with them."

Standardization is Schofield's next new school strategy for reducing expenses. This can be done with instruments and information systems. "Having disparate IT systems is a killer," noted Schofield. "This gets in the way of optimizing workflow, let alone intelligent cost-cutting and deeper integration.

"Standardization also is important for lab test utilization," he said. "NorDx uses a lab diagnostic committee that has laid the groundwork for installing utilization controls—meaning the parameters physicians will need to follow for population medicine.

"Another important way to reduce expenses is in lab administration," stated Schofield. "Labs should flatten their organizations. We've done that at NorDx and will continue to do so.

"Having more lab administrators than you need is a luxury labs can no longer afford," he said. "To be successful in the lab business today, no lab can be top-heavy. If it is, that fact will be evident in its metrics and in its benchmarking. For example, one lab's average costs-per-test will be higher than that of other labs, thus impeding its ability to compete effectively." TDR

—Joseph Burns

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Billing is Designed to Collect What's Owed

AT NORDX IN SCARBOROUGH, MAINE, the clinical lab has a billing staff of 12.55 full-time equivalent employees. Each member of the staff has a specialty and can provide cross-coverage as needed.

As part of the lab's new school strategy for getting paid, it has five specialists in billing who review claims from payers, each with a specific area of expertise. One is a specialist in bills that go to **Anthem**, for instance. One works with bills going to **MaineCare**, the state's Medicaid program. One is a federal programs specialist, handling Medicare claims. One specializes in serving client physicians and one is a specialist in collecting payments from patients.

The billing department also has exceptional productivity, said Stan Schofield, CEO of NorDx Laboratories. "Productivity significantly exceeds the most aggressive end of our consultant's benchmark range," he stated. "Each full-time equivalent staff member processes 172 requisitions per day and the benchmark range is 59 to 69 requisitions per FTE per day."

FDA Notifies Congress That It Will Regulate LDTs

➤Federal agency proposes risk-based oversight for 2,000 clinical laboratories offering 11,000 LDTs

➤➤CEO SUMMARY: Since 2006, the FDA has said it has the authority to regulate lab-developed tests, but it has held off on doing so. Now the agency says it's time, defining LDTs as being, "designed, manufactured, and used within a single laboratory. LDTs include some genetic tests and tests that are used by healthcare professionals to guide medical treatment for their patients." Following its notification to Congress, the FDA is expected to issue draft guidance on LDT regulation within 60 days.

THERE WERE PLENTY OF HEADLINES when the FDA disclosed to Congress on July 31 that it intended to regulate laboratory-developed tests. Buried in the reports, however, was the fact that the FDA had not yet released all the specifics about how it will regulate LDTs.

What triggered the news reports was a notice from the **Food and Drug Administration** to Congress that, within 60 days, it would issue draft guidance on how it would regulate LDTs. At that time, the FDA's proposal to regulate LDTs would be open for public comment for 90 days.

Under the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), the FDA must notify Congress of its intent to regulate LDTs. Specifically, the FDA said it proposed a risk-based oversight framework for what it estimated are 11,000 LDTs produced by 2,000 medical laboratories in the United States.

Laboratory-developed tests, the FDA explained, are, "designed, manufactured, and used within a single laboratory. They include some genetic tests and tests that are used by healthcare professionals to guide medical treatment for their patients. The FDA already oversees direct-to-consumer tests regardless of whether they are LDTs or traditional diagnostics."

➤FDA Offers Draft Guidance

In its notice to Congress, the FDA attached draft guidance titled, *Framework for Regulatory Oversight of Laboratory Developed Tests,* and a document titled *FDA Notification and Medical Device Reporting for Laboratory Developed Tests.* These documents and the letters to Congress are available online at *http://tinyurl.com/lqxoyp9*.

The FDA said it will use a risk-based, phased-in approach for oversight of LDTs. It further noted that its regulation of LDTs would be consistent with its regulation of *in vitro* diagnostic devices.

In response to the FDA's action, the law firm of **Wilson Sonsini Goodrich & Rosati** of Palo Alto, California, issued an alert last week explaining that the FDA's draft guidance has three regulatory levels for LDTs:

1) LDTs subject to full enforcement discretion (minimal regulation);
2) LDTs subject to partial enforcement discretion (moderate regulation); and,
3) LDTs subject to full FDA regulation.

Long Review, More Expense

"For companies that offer or plan to offer LDTs, the LDT classification is important because it determines the level of review by the FDA, with longer review times and more stringent review criteria translating into more time and expense to bring the LDT to market," the WSGR alert said.

The **Association for Molecular Pathology** (AMP) has members who will be directly affected by FDA regulation of LDTs. AMP's leadership has concerns about the FDA's proposal. "What we have is potentially a perfect storm," commented Elaine Lyon, Ph.D., President of AMP and Medical Director, Molecular Genetics; and Co-Medical Director, Pharmacogenomics, at **ARUP Laboratories** in Salt Lake City, Utah.

"Lab professionals should understand that the FDA is preparing to issue new regulations while—at the same time—the important questions about coverage and payment for molecular and genetic LDTs that were an issue last year continue to affect clinical laboratories today," added Lyon. "In addition, the FDA released the final guidance for companion diagnostics at the same time that they gave notice to Congress of its intent to release the framework for LDTs.

"We appreciate the fact that, in giving the notice to Congress, the FDA also released much of what it will propose," she continued. "AMP has found the FDA to be fairly open, despite the fact that the release is not final and the public comment period has not yet started.

"Having said that, we are deeply concerned that the FDA is making a significant change from the existing regulatory framework," Lyon added. "This change could dramatically impact laboratories that offer LDTs. In turn, this could affect how laboratories perform these tests and ultimately affect patient care."

The FDA said it will review the tests in the high-risk category first and then move to the moderate risk tests. Lyon observed that, "much remains unknown about the details of how the FDA will implement this draft guidance. For example, what is the definition of high risk and how many tests will be moved into this category? We don't know that yet.

"Of course, the main concern of AMP members is how these new regulations will affect patient care," she continued. "Often, laboratories offer LDTs for low-volume tests that have great importance for the few patients with uncommon diseases, yet these tests may not meet the FDA's definition of a rare disease.

"If the FDA's new regulations are overly burdensome, at what point would laboratories decide not to develop a test even though it's medically necessary?" she asked. "The burden created by regulations is an issue that needs to be considered. We want to ensure that laboratories will be able to continue to provide the tests they offer. That's a major concern."

Thousands Of LDTs

Lyon pointed out that another issue involves how the FDA would regulate the thousands of LDTs currently offered by laboratories across the country—while keeping up with the flood of new LDTs that continue to be developed in response to new scientific knowledge and advanced diagnostic technologies.

"The reality is that molecular laboratories today have few FDA-cleared assays available to them," she said. "They rely on lab-developed processes to develop tests that incorporate new knowledge and new technology.

"These laboratories are directed by physician pathologists, meaning M.D.s, or they are medically-boarded clinical scien-

Five Senators Sent Letter to OMB, Asking It to Release FDA's Draft Guidance on LDTs

WHY DID THE FDA CHOOSE THIS TIMING to commence the process necessary for it to regulate laboratory-developed tests? After all, it was as early as 2006 when the agency first proposed this idea.

The specific FDA draft guidance has been under review by the White House Office of Management and Budget (OMB), according to *The New York Times.* After the FDA proposed its plan to regulate LDTs in 2010, the idea ran into fierce opposition, reported *The Times*.

➤Did Politics Play A Role?

Politics may have had a role in the timing of the FDA's actions. For example, on July 2, five Democratic senators demanded that the proposal be released, said *The Times*.

In their letter to the OMB, the senators urged the OMB "to take prompt action in releasing this draft guidance on the regulation of laboratory developed tests, to ensure appropriate and efficient oversight of diagnostic tools can move forward in an open and transparent manner."

The five senators noted that "laboratories initially manufactured LDTs that were relatively simple, well understood pathology tests that could be used for low-risk diagnostics or for rare diseases for which adequate validation would not be feasible. These tests were traditionally developed to be used for a small population of local patients being evaluated by physicians at the same facility where the laboratory was located."

What has changed, wrote the senators, is that LDTs have become more complex and are a "staple of clinical decision-making and are being used to diagnose high-risk, but relatively common diseases... [Thus], it is imperative that they perform as they are expected." The senators asked OMB to release the draft guidance so that the FDA could solicit public comment and finalize the proposed rule.

Under law, the FDA must notify Congress 60 days before it plans to release the proposal. The agency delivered such a notice to Congress on July 31.

tists, meaning Ph.D.s," explained Lyon. "These well-trained individuals bring a strong professional component to the design, validation, implementation, review of the results, and the interpretation of the results based on clinical findings. This is significant and should be recognized by regulators and legislators.

➤Existing Lab Standards

"Further, the overwhelming majority of LDTs and laboratory-developed processes in use today come from CLIA laboratories," said Lyon. "Many of those CLIA laboratories also are CAP accredited. These laboratories already meet rigorous state, federal, and professional standards.

"So, to imply that LDTs are not regulated is not true," concluded Lyon. "In the United States, our laboratories are regulated and that regulation has worked very well since CLIA 1988."

Now that the FDA has provided notice to Congress that it intends to release its draft guidance for regulating laboratory-developed tests, knowledgeable observers expect that the next step that the agency takes will be to release the proposed guidance for LDT regulation.

This information will then be published in the *Federal Register* and the time period for public comment will be announced. During that public comment period, pathologists, Ph.D.s, and lab executives will have an opportunity to provide comments to the FDA. **TDR**

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There is a new case of crime involving a private pathology group practice. In Stockton, California, the *Stockton Record* reported on August 9 that pathologist Elvira Milano, M.D., was expected to post bond and be released from jail on that date. She faces charges of embezzlement while serving as chief financial officer of **Delta Pathology Associates Medical Group** (DPAMG) in Stockton. She was terminated on March 29, 2013, reported the *Record*, which also stated that court records indicate, "Milano used her control of the payroll to steal $503,202 from Delta Pathology from 2007-13. She is accused of taking $432,000 in excess payments in 2011 alone. In one 56-day span that year, she is alleged to have paid herself $421,000. Her annual salary that year was $226,200." Milano faces multiple charges in San Joaquin County Superior Court, with the possibility of jail time if convicted, stated the *Record*.

MORE ON: *Milano*

The *Stockton Record* also noted that Milano and another pathologist at DPAMG were co-defendants in a 2011 civil case involving their pathology group and **Integrated Pathology Services** of Stockton. As reported by the *Lodi News*, the plaintiffs were awarded a $2.8 million judgement for breach of contract and unfair business practices. The *Lodi News* said that Integrated had provided technical pathology services to DPAMG, but had not been paid for those services.

TRANSITIONS

• Matthew McManus, M.D., Ph.D., was appointed President and CEO of **Assuragen, Inc.**, of Austin, Texas. McManus has served as an executive at **PrimeraDx**, and **Cleveland Clinical Laboratories**.

• Al H. Sirmon, CPA, President of **PSA, a McKesson Company**, retired at the end of July. Prior to joining PSA, he held management positions with a clinical laboratory and **Pee Dee Pathology**, based in Florence, South Carolina.

• Chris Christopher has retired from his position as Vice President of Global Customer Solutions at **Siemens Healthcare**, effective at the end of July. Christopher held executive positions at **Dade Behring**, **Dade International**, and **Baxter**.

• **HemoSonics, LLC,** of Charlottesville, Virginia announced that Timothy J. Fischer is the new President and CEO. Fischer has previously served with **LipoScience**, **Becton, Dickinson**, **TriPath Oncology**, **Ventana Medical Systems**, and **Organon Teknika**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, September 2, 2014.