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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...

R. Lewis Dark
Founder & Publisher

NY Times Asks: 'Is Lab Testing the Wild West?'

HOW MANY OF YOU SAW THE NEWS STORY PUBLISHED LAST MONTH by *The Wall Street Journal* with the headline, "Is Lab Testing the 'Wild West' of Medicine?" It is the latest in a series of news stories about issues and questions involving the accuracy and quality of clinical laboratory tests delivered to patients daily here in the United States.

Journal reporter Thomas M. Burton's subhead read, "Largely unregulated industry comes under FDA scrutiny; lab-developed test providers fight back." He used that statement to frame the positions of the **Food and Drug Administration**, which is taking steps to regulate laboratory-developed tests (LDTs) versus those "laboratory-developed test providers" who are "fighting back."

Without stepping in the middle of the arguments for and against FDA regulation, I would like to call your attention to the more serious issue that is represented by the Journal's decision to research and write the story about the battle over federal regulation of LDTs. It reflects a recognition by the news media that consumers are interested in stories in which patients may be harmed because of problems in how a laboratory test was ordered, performed by the lab, and reported to the physician.

In recent years, the *Milwaukee Journal-Sentinel* has published well-researched stories about problems in state newborn screening programs, issues associated with how labs are licensed and accredited under CLIA, the lack of public transparency when CLIA assessors identify serious deficiencies that could cause patient harm, and related issues associated with the CLIA closure of the laboratory at **Marymount Hospital** in Cleveland last year.

Of course, the reported inaccuracies of lab tests performed on patients by **Theranos** in recent months have generated their own string of national news stories. All of these examples carry a message for pathologists and clinical laboratory executives: consumers (and the media) in the United States are raising the bar on the quality of lab testing services.

All laboratory organizations should recognize this change in the popular culture. The clinical lab profession would be well-served to set its own quality bar higher and exceed the expectations of its customers, including patients, physicians, payers, and even lab regulators. The fight over FDA regulation of LDTs is just one round in this new battle. TDR

Florida Legislators to Hold Hearing on Lab Utilization

Lawmakers take up clinical decision support systems and lab benefit management programs

CEO SUMMARY: Physicians in Florida and their state medical associations continue to battle UnitedHealth over its laboratory benefit management program that uses the lab test ordering system by BeaconLBS, a business unit of LabCorp. The latest round in this fight is language in a Florida Senate bill that would prohibit the use of a "clinical decision support system and a laboratory benefit management program in certain circumstances." A hearing on this bill will take place tomorrow.

IF IT TAKES PLACE TOMORROW as scheduled, a committee of the Florida legislature will hear testimony about the clinical decision support systems and laboratory benefit management programs health plans use to dictate how physicians may order laboratory tests.

This hearing is taking place because Senate Bill 1084 contains language that would prevent health insurers in Florida from requiring physicians to use such systems each time they order a laboratory test for their patients.

It is believed that this language was inserted into the proposed legislation because many physicians in Florida are unhappy with the laboratory benefit management program instituted last year by **UnitedHealthcare** and administered by **BeaconLBS**, a company owned by **Laboratory Corporation of America**. This program requires physicians, when treating patients enrolled in commercial UnitedHealthcare HMOs, to obtain pre-notification or pre-authorization for approximately 80 tests. *(See TDRs, July 21, and November 3, 2014, and February 17, 2015.)*

Over the past 18 months, many physicians and their state medical associations expressed serious criticisms of UHC's laboratory benefit management program and what they considered to be detrimental aspects in the design and operation of the BeaconLBS system they are required to use.

Florida Senate Bill 1084 includes language that would restrict the ability of health insurers to use systems designed to

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direct how physicians order laboratory tests in specific situations. The current language in the bill says, "…prohibiting a health maintenance organization from requiring that a healthcare provider use a clinical decision support system or a laboratory benefits management program in certain circumstances…"

It is expected that tomorrow's hearing will involve testimony from health insurers, physicians, and other experts. SB 1084 has many elements, so there may not be lengthy testimony regarding the wording of the restriction on the use of clinical decision support systems and laboratory benefit management programs.

It is significant that this language is included in the bill. It is evidence that the physician community remains unhappy with the design and operation of UHC's laboratory benefit management program and the requirement that they use the BeaconLBS system to obtain pre-notification or pre-authorization for as many as 80 lab tests.

Practice Of Medicine

Additionally, over the past 18 months, physicians and their state medical associations have regularly asserted that, by requiring them to use this lab test ordering system, UHC is interfering with their practice of medicine. Thus, the issue of control over how physicians order lab tests is just part of a greater battle that has existed in recent decades between health insurers—looking to control costs and encourage more appropriate utilization of clinical services—and physicians, who want the freedom to exercise their professional judgment when caring for their patients.

For their part, health plans, including UnitedHealthcare, have arguments in favor of using decision support systems to promote the use of evidence-based care. At tomorrow's hearings, it is possible that health insurers will cite statistics showing that the practice of medicine varies widely from one doctor to another and from one county to another. Health policy experts have been making this argument for years.

As of press time, UnitedHealth had declined to comment about SB 1084. Meanwhile, it is expected that news of this language in SB 1804 may encourage laboratories serving patients in Florida to submit comments to lawmakers as they continue to shape this bill. TDR

FL Bill Would Restrict Some Use of Lab Order Systems

NOW PENDING IN THE FLORIDA SENATE, SB 1084: Health Care Protocols, would be called the "Right Medicine Right Time Act." It would make changes to many aspects of how managed care plans, health insurers, and health maintenance organizations are allowed to conduct business. The bill also includes language that addresses the steps physicians need to follow when ordering prescription medications for patients.

The part of SB 1804 that deals with how physicians order lab tests says the following: "…prohibiting a health maintenance organization from requiring that a healthcare provider use a clinical decision support system or a laboratory benefits management program in certain circumstances…"

In explaining those circumstances, the bill says:

"A health maintenance organization may not require a healthcare provider, by contract with another healthcare provider, a patient, or another individual or entity, to use a clinical decision support system or a laboratory benefits management program before the provider may order clinical laboratory services or in an attempt to direct or limit the provider's medical decisionmaking relating to the use of such services.

"This subsection may not be construed to prohibit any prior authorization requirements that the health maintenance organization may have regarding the provision of clinical laboratory services."

Despite Tough AP Market, Bostwick Opens New Lab

Noted uropathologist says Granger Diagnostics aims to innovate, while holding lab costs down

CEO SUMMARY: Once again, entrepreneur and pathologist David G. Bostwick, MD, is starting up a new lab company. Granger Diagnostics is now open and is located in North Chesterfield, Virginia. It is designed to be an anatomic, clinical, and molecular pathology reference laboratory. In an exclusive interview, Bostwick identified three substantial changes that have happened to the anatomic pathology market in recent years and how Granger Laboratories intends to respond to those trends.

THERE'S A NEW LAB COMPANY, founded by pathologist-entrepreneur David Granger Bostwick, MD. Last month, he announced the formation of **Granger Diagnostics, LLC** in North Chesterfield, Virginia.

"Granger Diagnostics is a CLIA-certified anatomic, clinical, and molecular pathology reference laboratory that, like **Bostwick Laboratories**, specializes in the diagnosis and treatment of cancer and related conditions and has a strong focus on prostate cancer," stated Bostwick in an exclusive interview with THE DARK REPORT.

Nationwide Lab Network

Tests include anatomic pathology, FISH, molecular tests, and next-generation sequencing through a nationwide network of labs and affiliated labs. In addition to the lab in North Chesterfield, Granger has affiliated labs in Hapeville, Georgia, and it plans to open an affiliated lab in Orlando.

Granger Diagnostics launched with six employees, including Bostwick and one other pathologist, Jun Ma, MD, formerly of Bostwick Labs. Rosalind Baskette is the Director of Laboratory Operations. "We project having 25 employees, including five pathologists, by year end," stated Bostwick.

Granger Diagnostics currently has a hybrid sales staff of employees and contractors who operate along the east coast, in Arizona, and in other parts of the Southwest, he said. Plans are to expand to a sales force with nationwide coverage.

"It is time to return to my greatest passion in medicine: prostate cancer diagnosis and translational research," declared Bostwick. As he did at Bostwick Laboratories, which he founded in 1999, David Bostwick will serve as the Chief Medical Officer and will hire and train veteran pathologists and laboratorians.

"Here at Granger, we will have similar services as those that Bostwick had, meaning urologic and gynecologic pathology," he said. "The reason I left Bostwick Labs was that I sold the company in 2011 to **Metalmark Capital LLC,** a private equity firm. Metalmark then brought in a new team to run the operation.

"Although I remained at Bostwick after the sale, I wanted to run my own lab

again," explained Bostwick. "Once my non-compete agreement ended, I started this new lab company. I currently have no role at Bostwick Laboratories.

"Investors helped us get the new lab company up and running," he noted. "We also have a working relationship with **American International Biotechnology** (AIBioTech) of Richmond, Virginia. This is a genetics testing company that I've worked with for the past four years.

Sharing Common Services

"Granger Diagnostics is located in a building owned by AIBioTech and, on a contractual basis, we share their billing team, human resources, and some of their support staff to help us," noted Bostwick.

Despite all the market forces that have made anatomic pathology a difficult environment for pathologists, Bostwick has a positive outlook, noting, "In part, this is because we operate with a lean management structure, allowing us to devote a greater proportion of our resources to delivering clinical services.

"There have been three substantial changes in the anatomic pathology market over the past few years, and most of them are negative," observed Bostwick. "The first change was the government's decision to allow clinical labs to pay for electronic medical record systems for referring physicians. That practice is no longer legal. But when it was legal to do so, it put tremendous pressure on independent laboratories to market and pay for EHR systems.

"Independent labs had a difficult time competing against larger labs that had the resources to put those EHR systems in place wherever they needed them," he added. "In my opinion, implementing those EHR systems ultimately accomplished little or nothing for labs that did that for their clients.

"Second, the reimbursement rates for AP services have dropped considerably in recent years," he continued. "Price cuts to some AP services were so draconian that reimbursement is substantially less than what it costs a lab to perform those tests. Fortunately, reimbursement for other tests has risen so that—on balance—it is still possible for labs to make ends meet.

"However, for pathology labs to survive in this difficult financial environment, it is essential that overhead and all the costs of doing business be kept to a minimum," added Bostwick.

"Take the example of an independent anatomic pathology lab business with multiple managers and executives at the top," he said. "If these individuals are paid huge salaries while not contributing to revenue, that lab business will have trouble. The only way to make that overhead work is to be a very large laboratory with huge specimen volumes, such as **Quest Diagnostics** or **LabCorp**.

Restricting Access to Care

"The third significant change was the continued pressure by insurers and the government to restrict access to medical care and dictate what a physician and a pathologist can and cannot do," observed Bostwick. "By that I mean, for example, that payers told pathologists that they would be paid for a set number of prostate biopsies despite the number submitted by the urologist. At the same time, there were some important and contributory special stains that were prohibited or are now reimbursed at minimal rates.

Seeking Improved Efficiency

"This puts pathologists in the center of an interesting clinical and financial dilemma," Bostwick noted. "On one hand, the healthcare system demands that pathologists deliver more and more diagnostic services that are more complex and expensive. On the other hand, reimbursement is down. So pathologists must make up for that lower reimbursement with volume, and that requires running a highly efficient operation." TDR

—Joseph Burns

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Direct Access Test Labs Targeted by NY State AG

Direct Laboratory Services LLC, and LabCorp agree to pay fines and file compliance reports

CEO SUMMARY: Following an investigation of two lab companies providing direct access testing in New York State, the New York Attorney General entered into agreements with each lab company. Direct Laboratories, LLC, of Mandeville, Louisiana, agreed to cease offering DAT services in New York, pay restitution to patients, and pay a fine to the state. Laboratory Corporation of America agreed to pay a fine and report on its compliance efforts. The agreements reveal details of their DAT business model.

NEW YORK STATE PROHIBITS direct access testing (DAT). Just last month, the attorney general cracked down on two lab companies that were providing DAT services to consumers in the Empire State.

On December 30, Attorney General Eric T. Schneiderman announced agreements with **Direct Laboratories LLC** of Mandeville, Louisiana, and **Laboratory Corporation of America** to discontinue direct access testing services to residents of New York State.

The two settlement agreements provide a rare peek into the relationship that exists between a company offering DAT testing services and a national lab that contracts with it to collect the specimens and perform the testing, generally at a discounted price.

DirectLabs and LabCorp cooperated with Schneiderman's investigation, according to the individual settlement agreements with the AG's office. In March 2015, DirectLabs stopped offering services to New Yorkers and posted notices on its website that it was no longer operating in New York State, the agreement said.

DirectLabs was ordered to pay $24,500 as a civil penalty, pay $5,500 in restitution to patients whose tests were not completed, and stop all testing in New York State, although it continues to operate in other states. LabCorp agreed to pay a fine of $225,000.

The DirectLabs agreement explained that DirectLabs offers consumers nationwide direct access to more than 250 tests, meaning the patient does not need a physician's test requisition. "It does this by selling doctors' orders for the laboratory testing available through its website and partnering with LabCorp to have those orders accepted at LabCorp patient service centers," stated the agreement.

Direct Access Testing

Beginning in September 2012, DirectLabs operated a service called DirectLabs Access that was available to consumers in New York, New Jersey, and Rhode Island. Consumers could order tests online or by telephone without a requisition from a licensed physician or other health care provider, the agreement said. New York

law requires that laboratory tests be performed only at the request of licensed medical providers within their scope of practice.

After Schneiderman's office investigated the arrangement between DirectLabs and LabCorp, it ordered the operation to be shut down in March 2015.

"From September 2012 through March 2015, approximately 1,100 New Yorkers purchased diagnostic tests through DirectLabs, some of which cost hundreds of dollars. These tests may have been of little or no utility for any number of reasons, including that the tests were not medically appropriate for the consumer, or that the test results did not, in isolation, actually reflect that individual's likelihood of having the condition tested for," the agreement said.

One Chiropractor Listed

After getting a complaint about DirectLabs' practices in March 2015, the AG's office had a female investigator order seven tests through DirectLabs Access. "Under New York law, laboratories may only perform these tests at the request of a licensed provider, but the investigator was never examined by a licensed healthcare provider in connection with these tests. Moreover, the practitioner whose name appeared on the requisitions (and who was retained by DirectLabs to 'authorize' the laboratory tests purchased by consumers) was a chiropractor, and therefore could not legally order four of these tests (CA 27.29, RA factor, PSA, and tacrolimus)," the agreement said.

Investigation Begins

"The investigator intentionally purchased tests that, when performed without a healthcare provider's involvement, may disserve consumers. For example, the CA 27.29 test was described on DirectLabs' website as a way to evaluate possible progression of breast cancer, but this test is generally regarded as a poor clinical marker of breast cancer and is not recommended for routine surveillance of patients with breast cancer," the agreement said.

DirectLabs Charged $24

"After selecting the desired tests, consumers could proceed to check out. Upon checking out, DirectLabs charged a $24 'Access Portal Charge,'" the agreement said. "During the two and a half years it conducted business in New York, DirectLabs generated approximately $40,000 in revenue from issuing requisitions to New York consumers through the 'Access Portal Charges.'

"DirectLabs then sent consumers a requisition form for the selected tests that the consumer could bring to a LabCorp patient service center for the testing to be performed. Consumers would then pay LabCorp the price of the tests, as listed on the DirectLabs website (anywhere from $12 to over $5,000)," the agreement said.

Pathologists and lab executives may find this an interesting detail. DirectLabs charged a $24 fee to the consumer when the lab test order was placed. Then, upon arrival at the LabCorp PSC, the consumer was charged LabCorp's "EasyPay" fees. That meant DirectLabs was not collecting payment for the lab tests themselves.

Subpoena Issued By NY AG

On March 25, 2015, shortly after getting a subpoena from the New York AG, DirectLabs informed LabCorp that it would no longer operate in New York State. In October 2015, LabCorp terminated its contract with DirectLabs. "At the time that it terminated its contract with DirectLabs, LabCorp had no other contracts with virtual accounts offering direct access testing to New York consumers through the internet," the agreement said.

In addition to paying $225,000, LabCorp agreed to comply with certain requirements of the settlement and file reports about its compliance with the AG's office.

Settlement Agreements Spell Out Business Model for DAT Used by DirectLabs and LabCorp

DOCUMENTS FROM THE NEW YORK STATE ATTORNEY GENERAL show that LabCorp was the exclusive lab partner of DirectLabs for its direct access testing business in New York. These documents explain how the two labs worked together.

DirectLabs instructed customers to verify that a LabCorp location was nearby, to bring the DirectLabs requisition to LabCorp, then pay LabCorp for the testing "at special rates to DirectLabs customers," the agreement said. After consumers brought their requisitions to LabCorp PSCs and had their specimens drawn, LabCorp made the results available to DirectLabs through an online portal.

"In 2012, LabCorp contracted with DirectLabs to process requisitions for laboratory testing submitted by DirectLabs in New York, at a fee schedule negotiated by the parties," the agreement said. "Pursuant to a separate management agreement, LabCorp provided DirectLabs access to an electronic interface that enabled DirectLabs to generate requisitions for laboratory tests, transmit customer information to LabCorp, and receive its customers' test results. LabCorp also provided DirectLabs with requisition forms, report papers, and printing accessories," the agreement said.

LabCorp's contract with DirectLabs required that, "before submitting a requisition for laboratory testing… [DirectLabs] shall ensure that all requests for tests have been reviewed and approved by a physician licensed in the applicable patient's state of residence," the agreement said.

"When DirectLabs customers appeared at New York LabCorp PSCs with DirectLabs-issued requisitions, LabCorp staff did not check whether a New York-licensed healthcare provider (HCP), acting within the scope of their license requested the testing, or whether New York-licensed HCPs examined those patients before taking and examining specimens from those consumers," the agreement said. "In some instances, for unknown reasons, the names of other non-New York HCPs appeared on requisitions generated internally by LabCorp," the agreement added.

"LabCorp processed approximately 130 tests listed on DirectLabs-issued requisitions that are outside a chiropractor's scope of practice, including tests for cancer antigen, rheumatoid arthritis factor, prostate specific antigen, and tacrolimus," the agreement said.

"LabCorp considered DirectLabs to be a 'virtual account," a company not located in a typical medical practice that owns a web site that offers consumers direct access testing. Since 2009, LabCorp has maintained a diligence checklist for its 'virtual accounts' in which LabCorp assesses, among other things, whether the account has a licensed healthcare provider on staff and contracted to order testing in each state, and how the account will document that the licensed ordering provider approved the request that a test be performed. LabCorp did not complete the diligence checklist for DirectLabs because it already had a contract with that entity that addressed these items," the agreement said.

DirectLabs paid $24,500 plus $5,500 in restitution, and was ordered to track which customers processed their refund payments and "make all commercially reasonable efforts to refund all customers with unused requisitions." DirectLabs also agreed to file compliance reports with New York State.

Within 210 days of the date of the agreement, DirectLabs was ordered to pay the AG the difference between $5,472 (the total amount of potential refund payments) and the actual amount in refunds. TDR

—Joseph Burns

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Doctors Can Order From Molecular Test Database

New Company Tracks Price Information for 60,000 Genetic Tests

CEO SUMMARY: Advances in the speed, accuracy, and cost of next-generation gene sequencing making it possible for clinical labs to create thousands of new tests. How many new tests? NextGxDx, an information technology company, says the nation's clinical laboratories are introducing new molecular and genetic tests at the rate of 10 per day! The company, in Franklin, Tennessee, has compiled a database that contains 60,000 of these tests, along with detailed specifications and prices. Hospitals are using this database to select appropriate genetic tests and reduce the cost of testing.

CLINICAL LABORATORIES ARE INTRODUCING 10 new molecular and genetic tests every day, a rate of growth that has produced 60,000 tests currently available for clinical use!

THE DARK REPORT is first to publish this remarkable number. Among other things, it helps to explain why Medicare and private payers are finding it impossible to stay up with all the requests from labs to establish coverage guidelines and reimbursement for these new lab tests.

This information was developed by a new company, **NextGxDx Inc.** of Nashville. It has assembled an extensive data base of molecular and genetic tests offered for clinical use, and, for the past two years, NextGxDx has tracked the details for each of these 60,000 tests.

"The rising number of testing products makes it all but impossible for clinical laboratory directors, pathologists, and treating physicians to know what's available, which tests are comparable, and which are best for their patients," observed Jud Schneider, PhD, NextGxDx's Vice President of Bioinformatics.

"With tens of thousands of assays being offered by hundreds of clinical labs, we recognized the need for an online catalog and a curator who can collect all the information on these tests and group them into clinically relevant categories," he continued. "Such a catalog makes it possible for pathologists and laboratory scientists to track the development of new tests and compare new tests to existing tests."

The foundation for such a curated catalog exists. **The Human Genome Nomenclature Consortium** (HGNC) approves the unique symbols and names for human genes. Designed to foster communication in the scientific community, HGNC runs a website at *genenames.org* that is a curated database of gene nomenclature and families, and other resources for scientists and clinicians involved in both research and clinical care.

But curating the various testing products to identify those genes and gene mutations may be a more complex endeavor. That's where NextGxDx has developed a niche. An information technology company, NextGxDx seeks to improve the genetic test ordering process for clinicians by offering two services: GeneSource and GeneConnect.

"Each of these services draws upon extensive data—including product attributes, turnaround time, and list prices—for each genetic and molecular test listed in our catalog," stated Schneider. "Of course, we may not have a price for each test tracked in our database because not all labs publish their prices. Nonetheless, because we update all the prices we can access monthly, our database is a reliable source for prices and pricing trends of molecular and genetic tests."

In a recent interview with the editors of THE DARK REPORT, Schneider and Gillian Hooker, PhD, Vice President of Clinical Development at NextGxDx and a genetic counselor by training, talked about the two products, GeneSource and GeneConnect, how NextGxDx collects the data on the 60,000 tests in its database, and how it identifies trends in the pricing of genetic tests.

Manual Processes Will Fail

"The genetic testing market is growing so rapidly that manual processes to stay on top of it—such as binders or documents in a file—are no longer sufficient," noted Schneider. "The volume of current testing products and the rapid development of new products requires a searchable, online database, along with a rigorous curating system to manage that data."

Hooker explained how NextGxDx works. "The best way to think about our company is that we have a core database of information on more than 60,000 different testing products now on the market," she stated. "It's up-to-date, comprehensive and includes all testing products, such as genetic and molecular tests for cancer and other conditions. The clients who can benefit from using our two products include clinical labs, clinicians, and hospitals.

"The first product we launched was GeneSource, which is a freely available public website designed to meet the needs of clinicians," she said. "GeneSource is a genetic testing database and online marketplace that allows treating physicians and other providers to view a list of all genetic tests from CLIA-certified laboratories.

Pertinent Information

"Not only can they can see pertinent information about each test," added Hooker, "but providers logged into GeneSource can then order tests online and manage results electronically within a HIPAA-compliant portal.

"Ordering clinicians use it to find genetic tests for specific conditions and to search and compare one test against other tests in a way that is clinically intuitive," she said. "Our bioinformatics team organizes these molecular and genetic tests so that clinicians can view and compare them side by side and then order one."

In the two years since GeneSource was introduced, the company says it has built a base of clinicians and laboratory users that includes individuals from:

- 14 of the top 15 adult hospitals
- 10 of the top 12 children's hospitals
- 37 of the top 50 hospitals for neurology
- 34 of the top 50 hospitals for cardiology
- 39 of the top 50 hospitals for cancer.

Tracking and Managing Tests

"Our other product, GeneConnect, is designed for hospitals to enhance and simplify their utilization management," explained Hooker. "GeneConnect lets hospitals streamline the process. It does so by: 1) helping hospital labs document preferred relationships with reference labs, 2) by tracking electronic orders and results, and 3) by monitoring test utilization."

The GeneConnect platform has signed a growing list of leading institutions. These include three of the top six children's hospitals. Among these is **Seattle Children's Hospital**, which is well-known for its Pediatric Laboratory Utilization Management Services (PLUGS) program. *(See TDR, April 20, 2015.)*

"Hospitals have a diverse array of tests that they order and, in particular, they need a way to manage molecular and genetic tests," she said. "They order these tests through GeneConnect because then they can track their orders and manage their relationships with the labs that offer these tests.

"Another benefit of the GeneConnect service is that it is designed to help hospital labs better manage the cost of genetic test sendouts," Hooker noted. "It allows them to see where they are spending money and where they are losing money. This allows them to identify opportunities to make informed choices.

Identify Comparable Tests

"Pathologists supervising hospital laboratories know how expensive many genetic tests are," she stated. "Our hospital clients are finding it much easier to use the data base that has information about 60,000 molecular and genetic tests to identify comparable tests that are less expensive. In turn, that opens an opportunity to reduce per-test costs for send-out genetic tests in their lab."

Clinical laboratories and anatomic pathology groups across the United States will see another benefit from NextGxDx's effort to assemble this database of genetic tests and the prices for these tests. The company is producing data on the prices for the same type of molecular and genetic test data, along with the changes in these prices over time. It will be the lab industry's first opportunity to have reliable information on pricing trends for such tests.

How does NextGxDx get regular pricing data on 60,000 tests from hundreds of labs without making phone calls? "We've built software with the capability to pull detailed data directly from the website of the lab organizations that offer molecular and genetic tests for clinical purposes," stated Schneider. "It is not necessary for

Designing a Way to Track 60,000 Genetic Tests Requires a Big Database and Analytical Tools

KEEPING TRACK OF MORE THAN **60,000** MOLECULAR AND GENETIC TESTS is a problem unseen in the clinical laboratory industry until recent years. To build its GeneSource database of this information and keep it up to date, NextGxDx uses a three-step process.

"The first step is to regularly collect data from more than 300 labs, primarily from their websites," noted Jud Schneider, PhD, NextGxDx VP of Bioinformatics. "We also collect data from journals, reports, and any other reliable sources of information we can find.

"Step two is to convert that data into structured information," he said. "One way we do this is by standardizing the terminology. We start with the terms already used in known standards such the Online Mendelian Inheritance in Man. OMIM is a catalog of human genes, genetic disorders, and traits that focuses on the molecular relationship between genetic variation and phenotypic expression. It is a companion to the Human Genome Project. We also use HGNC.

"Should there be no published standards for a particular test, we develop them," explained Schneider. "For example, we've developed standards to describe the different attributes of tests that did not exist previously.

"Step three happens after we collect the data," he noted. "Each molecular and genetic test is put into a category, a process we call binning. Each test is assessed, then added to the categories of tests that are clinically comparable.

"That way, whenever a pathologist, for example, searches the GeneSource database, he or she will see all the categories of tests and each category is in one of our bins. Next, the pathologist or a physician who is ready to order a test can dive down into that bin to discover the specific products in that category.

"Once the data about these 60,000 molecular and genetic tests are in place, we then maintain that database," Schneider said. "Along with regular updates from the source labs, we do audits of some of the information and continual quality improvement, and we use algorithms that sift through the data to identify and correct errors."

those labs to submit that pricing data to us. We collect it automatically.

"Of course, we can only see lab test prices that are publicly available," he emphasized. "Not all lab organizations publish their prices, but a significant number of them do. That is the source of our pricing data."

Decline In Published Prices

Schneider and Hooker revealed that, over the past two years, competition among labs developing molecular and genetic tests continually increased, correlating with a decline in published prices. "Looking at the prices for molecular and genetic tests that were published, we tracked a significant overall decrease of 14% in the list prices of tests from early 2014 through the end of 2015," stated Schneider. "Single gene tests dropped in price by 15%, panel tests dropped by 8%, and whole exome tests dropped by about 13%.

"Interesting changes in prices can be seen," he said. "For example, we observed the price of single gene tests dropped more than the price of gene panels from 2014 to 2015. We think that's because next-generation sequencing is starting to supplant Sanger sequencing in laboratories.

"Many NGS panels were launched in 2013 and 2014, and prices for these tests did not decrease as much as the prices for single gene tests," Schneider noted. "We also know that many panels done with Sanger sequencing are still offered and have not changed much in price.

"Another significant trend we observed is how some hospitals and ordering physi-

cians are shifting their orders to NGS-based products and panels because they see that the costs are lower and the quality is the same or slightly better," he continued. "Increasingly, next-gen sequencing is being recognized as a viable technology that is, in some cases, better than Sanger sequencing for specific applications. Also, we see hospitals and ordering physicians shifting more of their single gene tests into assays that incorporate NGS as well."

At this point, Schneider added an observation about pricing trends. "From these numbers, we draw two inferences about the dynamics in the molecular and gene testing market," he said. "The first is that increased competition is affecting price. Given that we're drawing information and pricing data from about 300 labs, and many offer similar tests, we presume some labs reduce prices to capture more market share. The second factor is that many labs recognize that reimbursement from health plans and other payers is increasingly selective, and that patients often bear a significant share of costs."

Forms of Pricing Pressure

"That is an additional source of pricing pressure and labs that offer molecular and genetic tests are responding to this pressure," commented Hooker. "As a genetic counselor, over the past several years, we hear from many patients who received bills for molecular and genetic tests that amount to thousands of dollars.

"Costs can be so high that—even after the health plan pays the hospital—the patient has to pay the remainder and those amounts can be distressing for everyone," she explained. "Consequently, there is continual pressure from many parties to move away from extremely high-priced genetic tests whenever possible. And NGS gives labs and hospitals an opportunity to do so.

"Another factor contributing to lower prices for genetic tests is supply and demand," she stated. "More labs that provide the same test are entering the market.

"We studied price data from labs offering the same genetic tests," continued Hooker. "We put prices for whole exome sequencing tests from September 2014 to September 2015 into a chart and compared that with the growth in exome products offered.

Decrease in List Prices

"We saw that the price of exome sequencing tests dropped significantly," she noted. "List prices decreased from an average of over $7,000 to about $5,000 to $5,500. This is evidence that increased competition in the genetic testing market will be good for patients, payers, and any provider or payer sensitive to high prices."

Schneider pointed out that, among the more than 300 labs from which NextGxDx pulls data, not all labs offer all molecular and genetic tests. "There are numerous specialty lab test companies that may offer one or several tests," he observed. "Then there are labs that have large catalogs of genetic and molecular tests that they offer. These labs include **Seattle Children's**, **Claritas Genomics**, **CTGT**, **MNG Laboratories**, **Cincinnati Children's**, and many academic medical center labs.

"Two other labs that have large test catalogs are **Prevention Genetics** and **Fulgent**," Hooker added. "In fact, Prevention's catalog is one of the largest that we track in the United States."

Growth in NGS

Schneider explained that the market for molecular and genetic tests is growing so quickly that it would be impossible to keep pace with the need for increased data on tests and prices without an online catalog such as the one NextGxDx has built.

"On average, we update every product in our database every two weeks, and we do that by processing about 3 million data points each month," he commented. "Considering how quickly the number of molecular and genetic tests is growing, any type of manual process designed to

Understanding the Ongoing Explosive Growth in Number of Molecular and Genetic Tests

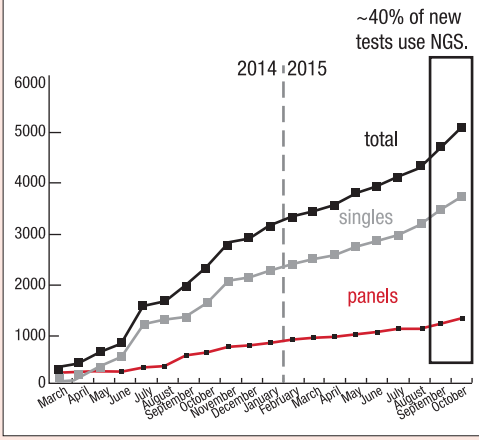
THESE TWO CHARTS DEMONSTRATE the astounding rate of growth in the number and variety of molecular assays and genetic tests, as tracked by NextGxDx.

Chart A: shows the total number of tests each month, along with the number of offerings that are panels and single gene tests. NextGxDx says that 40% of these incorporate next-generation gene sequencing. As of December 2015, labs offered more than 60,000 unique tests.

Chart B: illustrates how many tests that incorporate specific genetic markers are available in the market. For example, in September 2014, there were 110 tests offered. That number had increased to 355 by September 2015.

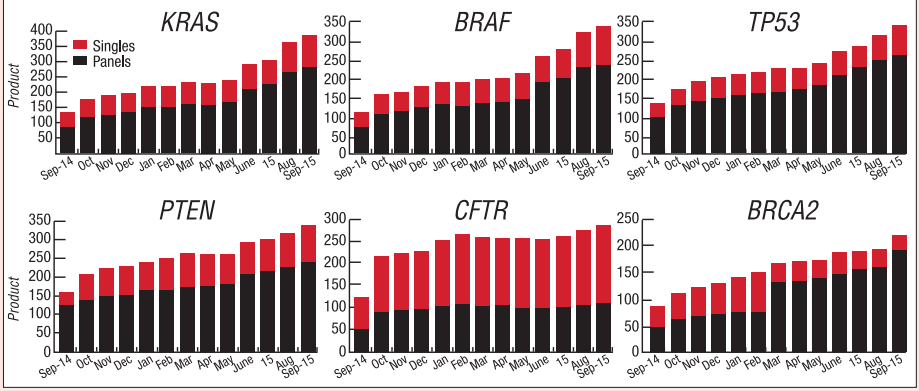
A. Growth in Genetic Tests

(By Month, Mar. 2014–Oct. 2015)



B. Number of New Genetic Tests

(By Month, Sept. 2014–Sept. 2015)



get a handle on this sector of the lab testing market is doomed to fail."

What is significant about NextGxDx is that, if information is power, then this company is positioning itself to be a major player in genetic testing. If it can show its clients—hospitals that are ordering expensive genetic tests—how to use that data to lower the cost of send-out testing while still achieving improved patient outcomes, then NextGxDx may find itself enjoying first-mover advantage in the fast-developing field of genetic testing.

Further, although Schneider and Hooker did not discuss how Medicare administrative contractors (MACs) and private health insurance companies could use its database of molecular and genetic tests, it probably won't be long before health insurers begin to tap that database to help them establish coverage guidelines and prices for these assays. **TDR**

—Joseph Burns

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Lab Market Update

After Theranos-Safeway Split, Grocer Picks Sonora Quest

Arizona's largest clinical lab company opens PSCs in Safeway stores in Phoenix, Scottsdale

IT'S RARE TO FIND ONE COMPANY STEP IN after another fails to execute a business strategy successfully. But that happened when **Sonora Quest Laboratories** in Scottsdale, Arizona, moved to fill the void created when **Theranos Inc.** did not fulfill an agreement to open patient service centers (PSCs) in Safeway stores in Arizona.

Since last month, Sonora Quest has opened patient services centers in two Safeway stores. In November, it was reported by *The Wall Street Journal* that Theranos had planned to open PSCs in 800 Safeway stores nationwide. To accommodate these centers, Safeway spent $350 million to build the infrastructure Theranos would need. *The Journal* also reported that Theranos and Safeway were negotiating to dissolve their agreement.

Empowering Patients

"We're excited about the opportunity to open these two patient service centers in a retail setting," stated Christina Noble, VP of Business Development at Sonora Quest. "We have a strong belief in patient empowerment and making lab tests available in food and drug retailers is one more way to support patients while improving patient satisfaction and the patient experience.

"It could be that operating in a convenient environment such as grocery stores will allow patients to improve their adherence to doctors' orders for testing," she noted. "That could help to control costs for patients and for health plans and government payers as well."

Sonora Quest opened one PSC in a Safeway store in north Scottsdale. Another is open in Phoenix. Each PSC is open from 7 am to 6 pm on weekdays and 8 am to noon on Saturdays. "Sonora Quest is continually re-evaluating its options to see if and where it would be most appropriate to open other PSCs in a Safeway or other retail setting," observed Noble.

"All of our patient service centers—including the ones in Safeway stores—are full service centers," she explained. "That means a patient can obtain any test ordered by his or her physician, not just the menu of tests that we offer under the state's direct-access testing law. All patient samples collected at our PSCs in Safeway are tested in our core lab." *(See TDR, November 16, 2015.)*

According to *The Wall Street Journal,* along with collecting specimens from consumers and patients, Theranos had planned to do some lab testing onsite in Safeway stores as a way to deliver results quickly to patients. It is reported that as many as 800 Safeway stores were remodeled with waiting areas and spaces where specimens could be collected and lab tests performed on site.

Meanwhile, the team at Sonora Quest sees opportunity in direct access testing. "For us and for the clinical lab industry, this is an exciting challenge. It's time for labs to make it easier for patients to get lab testing done," concluded Noble. TDR

—Joseph Burns

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LabCorp to Purchase Pathology, Inc. in Calif.

Lab company 'will cease operations' while pathologists will continue in private practice

CEO SUMMARY: It is one of those clinical laboratory deals that was announced before the end of 2015. Laboratory Corporation of America said it will acquire most of the operating assets of Pathology Inc., of Torrance, California, and that the acquired lab "will cease operations" upon the closing of the transaction. It has been six years since venture capitalists invested in Pathology Inc., so the timing of this sale may also be due to the need among the venture capitalists to liquidate this investment.

IN DECEMBER, **Laboratory Corporation of America** said it planned to acquire "substantially all of the operating assets" of **Pathology, Inc.**, in Torrance, California, including the company's patient service centers.

In its announcement of the deal, LabCorp said, "Upon the closing of the transaction, Pathology, Inc., will cease operations."

When asked by THE DARK REPORT to comment on the sale, Pathology Inc.'s CEO and President, Vicki DiFrancesco, said the company was "unable to speak until after regulatory review." The transaction is on hold until the waiting period expires under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. That puts the anticipated time to close the deal in the first quarter of 2016. Terms of the agreement were not disclosed.

The use of an asset sale is typical when the buyer wants the client list, the lab facilities, and lab equipment. Pathology Inc. has 16 pathologists and the press release did not address if they would continue to practice as employees of LabCorp or whether the pathologists will form a professional corporation and use that to contract their services to LabCorp once the sale closes.

Fourteen of the pathology lab company's pathologists are also part of **Affiliated Pathologists Medical Group** (APMG), a professional corporation based in Rancho Domingo, California. APMG says it is comprised of "38 board certified, and—in many instances subspecialty-certified—pathologists covering 11 service locations in four counties in California, one county in Phoenix, and two counties in Portland, Oregon."

Women's Health Laboratory

Pathology, Inc., describes itself as a "full-service independent women's health laboratory, providing expertise in reproductive FDA donor testing as well as anatomic, molecular and digital pathology services." It offers pathology services in six subspecialties.

The facts that Pathology Inc. was for sale and that the buyer was LabCorp were no surprise, for two reasons. First, in

recent years, it was rumored more than once that the pathology lab company was for sale. It was believed that the venture capital company that owned equity in Pathology Inc. was ready to harvest its investment.

Second, Pathology Inc.'s Chairman and its CEO each had a long-standing relationship with LabCorp. In the case of Alfred Lui, MD, Chairman, he had sold his clinical lab company to LabCorp in 2000. Since then, he has served as the medical director for some of LabCorp's clinical labs in Southern California.

Pathology Inc.'s CEO and President, Vicki DiFrancesco, is an experienced and successful lab executive and sales professional who worked at **National Health Laboratories** before it merged with LabCorp and she worked at LabCorp after the merger. She thus has had extensive working relationships with several of LabCorp's key executives.

These multi-year business relationships between the principals of Pathology Inc. and LabCorp probably played a role in the sales negotiations. Both parties had direct experience with each other.

Venture Capital Investment

Looking back over the history of Pathology Inc., it is worth noting that the company accepted a capital investment in 2009 from **ABS Capital Partners**, along with venture capital debt from **ORIX Venture Finance LLC**. At the time, Pathology Inc. described ABS Capital Partners as a leading later-stage growth company investor.

During this capitalization, the pathology laboratory company named DiFrancesco as CEO and Steve Pierce as CFO. Pierce had served as CFO of **US Pathology Labs, Inc.** (**US LABS**), a company also funded by ABS Capital that was sold to LabCorp in 2004. TDR

—Joseph Burns

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Entrepreneurial Pathologist Founded, Bought, & Sold Labs

EARLY IN HIS CAREER, pathologist Al Lui, MD, showed his entrepreneurial interest and skills. In 1981, he founded a clinical laboratory company known as **Bio-Diagnostic Laboratories** in Southern California.

In 1985, Lui sold a substantial minority interest in BDL to **Nichols Institute**, then operated by CEO Albert Nichols, MD. However, the two Als did not see eye-to-eye. Within a few years, Nichols had sold his interest back to Lui.

Fast forward to the year 2000. In response to the deeply-discounted, full-risk capitated contracts that were common in California during those years, Lui made the decision to sell Bio-Diagnostic Laboratories. At that time, BDL had annual revenue of $12 million. The buyer was Laboratory Corporation of America, a company for which Lui's pathology group had been providing contract services during the prior year. *(See TDR, May 15, 2000.)*

At the time of the sale, Lui explained that the transaction allowed the pathologists associated with BDL to concentrate exclusively on pathology. "We decided to sell Bio-Diagnostic Laboratories at this time because we wanted to concentrate on our core competency, which is pathology," he said.

This group was Affiliated Pathologists Medical Group (APMG), a professional corporation. In subsequent years, Lui and his colleagues expanded APMG in California while developing business in both Arizona and Oregon.

To develop capabilities in clinical laboratory and pathology testing still further, Lui worked with the venture capitalists and, in 2009, Pathology, Inc., was formed and capitalized. In 2011, **Pathology Holdings, Inc.**, the parent company of Pathology, Inc., acquired **Central Coast Clinical Laboratories** of Templeton, California.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Sakura Finetek USA, Inc., announced on January 5 that it had acquired 100% of the stock of **GeneMed Biotechnologies Inc.**, of South San Francisco, California, along with its "tissue-based advanced staining business for cancer detection, diagnosis, and monitoring." GeneMed's liquid-based molecular products were not part of the acquisition and will be put into an independent business. Takashi Tsuzki, CEO and President of Sakura Finetek USA, noted that GeneMed's products—including antibodies, detection systems, ISH probes, and ancillary reagents—were complementary with Sakura's products used in routine staining. The GeneMed products will help Sakura serve the advanced staining market.

ADD TO: *Sakura Finetek*

Sakura Finetek's acquisition of Genemed is another example of consolidation in the IVD and histology sectors, where the need to have size and scale is a critical success factor. It also illustrates another trend, which is the desire of lab vendors to offer a complete range of solutions to their lab customers. In a press release, Sakura Finetek Europe noted that GeneMed manufactures 111 primary antibodies, 9 detection systems, 22 ISH probes, and 35 ancillary reagents.

INDEPENDENCE BC FIRST TO PAY FOR WHOLE GENOME SEQUENCING

Earlier this month, **Independence Blue Cross** of Philadelphia announced that it would cover "next generation whole genome sequencing for a variety of cancers." It is the first health insurer in the nation to cover whole genome sequencing. **NantHealth** of Culver City, California, will provide the next-generation gene sequencing for patients insured by Independence Blue Cross. This coverage begins in March and, according to the company's press release, "The test will be covered for members with specific conditions including rare cancers, tumors in children, metastatic cancer of unknown primary, primary brain cancer, triple negative breast cancer, and metastatic cancer where conventional therapies have been exhausted and patients remain candidates for further therapy."

TRANSITIONS

• **Counsyl, Inc.**, of South San Francisco, California, named Ted Snellgrove as its new Chief Business Officer. He has held formerly executive positions with **Jazz Pharmaceuticals**, **Cellscape Corporation**, **Crescendo Bioscience**, and **Genomic Health**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 8, 2016.