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YEAR-END ISSUE
TOP 10 LAB STORIES >>2015

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Lab Industry's Non-Stories for 2015

AT THE END OF EACH YEAR, IT IS GENERALLY EASY TO PICK OUT the stories of greatest significance for the lab industry during the previous 12 months. But what is often overlooked are the non-stories. These are the events that did not happen in the year, despite earlier occurrences and the momentum pushing certain trends forward.

During 2015, three stories meet the non-story definition. Prior to the start of the year, many experts expected that each of these stories would have significant influence on healthcare and the clinical lab industry. Events turned out differently.

The first non-story is implementation of ICD-10. On October 1, 2015, ICD-10 diagnosis codes replaced those of ICD-9. Despite all the fears and predictions of chaos in the coding and payment for provider claims, it turned out to be a non-event. Now, almost 90 days into the ICD-10 era, it is difficult to find a news story that reports major problems in how Medicare and private insurers are paying hospitals, physicians, and labs. Given the potential for severe financial disruption, this is good news for all providers.

The second non-story centers upon the lack of accelerated progress in the adoption and operation of integrated care organizations such as accountable care organizations (ACOs) and patient-centered medical homes (PCMHs) during 2015. Although the number of ACOs increased modestly during the year, collectively, ACOs and PCMHs did not greatly change the existing relationships between hospitals, physicians, and ancillary providers, including clinical labs. There was only modest progress in integrating care delivery among providers participating in ACOs, but also during 2015, most payments to providers continued as reduced fee-for-service with a year-end distribution calculated from savings in the ACO's projected cost of care.

The third non-story during 2015 involves Meaningful Use Stage 2 and Stage 3 requirements. Unlike the early years of this federal program to encourage hospitals and physicians to adopt electronic health records, clinical labs and pathology groups were under much less pressure from clients to create LIS-to-EHR interfaces. Even the publication of proposed rules for Meaningful Use Stage 3 during 2015 did not generate much concern about compliance among providers. TDR

2015's Top 10 Lab Stories Show Significant Changes

One insight is that healthcare and the lab industry may experience faster transformation after 2015

CEO SUMMARY: During 2015, two stories captured the full attention of most pathologists and clinical lab managers. One was how CMS intends to gather lab price market data as mandated by PAMA. The other was the continued efforts by the FDA to move ahead on proposed guidance for regulation of LDTs. However, the full list of THE DARK REPORT's "Top 10 Lab Industry Stories for 2015" includes additional developments with the potential to radically change the lab industry as it operates today.

IT WOULD BE EASY TO CHARACTERIZE 2015 as a quiet year for clinical labs and pathology groups. But that hides the reality of how, over the course of 2015, several significant developments took place that will greatly influence the clinical, financial, and operational aspects of laboratory medicine for years to come.

In presenting THE DARK REPORT's list of the "Top 10 Lab Industry Stories for 2015," the goal is to identify the year's most important events through news stories of significance during the year. It is an effective way to understand major trends in the U.S. healthcare system and the clinical laboratory marketplace.

It was a year when acronyms dominated the headlines of lab industry stories: CMS, PAMA (lab price marketing reporting), ADLT, FDA, and LDT. These acronyms represent a federal government agency, new definitions, and activities that will directly cause changes in how labs provide clinical services and get paid.

Of greatest concern to the lab industry are proposed rules by the **Centers for Medicare & Medicaid Services** and the **Food and Drug Administration** issued in 2015. The two agencies have yet to finalize and implement their respective proposed rules. That is expected to happen during 2016. *(See story one, page 5.)*

In the case of CMS, this fall it issued the proposed rule to implement the lab test market reporting requirements of the Protecting Access to Medicare Act of 2014 (PAMA). CMS missed the deadline mandated by PAMA for releasing this rule.

Meanwhile, the FDA issued its draft guidance for regulatory oversight in late

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2014 and has taken additional steps during 2015. This year, the FDA gathered input from stakeholders, including clinical laboratories and *in vitro* diagnostics manufacturers. It also testified at a hearing in Congress last month about LDT regulation.

2015 Was A Watershed Year

In this regard, in coming years when lab administrators and pathologists look back on 2015, they will probably consider this to be the watershed year when everything that followed in the lab testing marketplace was much different than what happened in the years prior to 2015.

One reason is the expanding use of new diagnostic technologies by clinical labs. Faced with a flood of new molecular and genetic tests, government and private payers are unable to develop coverage guidelines and pricing in a timely fashion. Instead, many health insurers are simply deciding not to cover most new genetic tests. *(See story two, page 5.)*

One response to this trend was some payers required pre-authorization of certain clinical laboratory and genetic tests. The pilot laboratory benefit management program that **UnitedHealthcare** launched in early 2015 for some of its health plans got the most attention. But the year ended with **Blue Cross Blue Shield of South Carolina** implementing its own lab test pre-authorization program that is administered by a new lab benefit management company. *(See story 4, page 6.)*

The health insurance industry took other actions during 2015 that had significant financial consequences for nearly all the nation's clinical laboratories and pathology groups. Some national health insurers got much tougher when auditing labs. In particular, they wanted documentation that the labs had been collecting copays and deductibles from patients. *(See story six on page 7.)*

National news coverage of federal whistleblower lawsuits against lab companies that settled in 2015 brought attention to a growing problem within the clinical lab industry: fraud and abuse on an unprecedented scale. In court documents the **Department of Justice** filed during the summer against the principals involved with **Health Diagnostic Laboratories** of Richmond, Virginia, for example, federal prosecutors claimed that the Medicare and Tricare programs had paid HDL more than $500 million in 60 months between 2010 and 2014!

This fall, **Millennium Health**, a toxicology testing company, agreed to pay $256 million to settle its *qui tam* case for alleged false claims submitted from 2008 through May 2015.

It is estimated that just these two lab companies generated $1 billion in Medicare payments using, as described in court documents, inducement schemes that violated federal and state antikickback laws. This fraudulent activity has Medicare officials on the alert and motivated several private health insurers to file civil lawsuits against lab companies they claim are engaged in fraudulent billing practices. *(See story three, page 6.)*

Ups And Downs At Theranos

Of course, no list of the 10 biggest lab industry stories for 2015 would be complete without including **Theranos, Inc.**, the controversial lab testing company based in Palo Alto, California. As 2015 opened, Theranos was the darling of the business press and was hailed as poised to disrupt the clinical lab industry. In Phoenix, it was offering lab testing in about 40 **Walgreens** Pharmacies. However, as 2015 closed, Theranos was in full defensive mode, after a series of investigative news stories in *The Wall Street Journal* revealed serious problems Theranos was having with its proprietary technology. *(See story 10, page 9.)*

THE DARK REPORT encourages you to use this list of the 10 biggest lab industry stories for 2015 as the basis for strategic planning at your lab organization. TDR

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2015 TOP TEN 1

Fed Regulators Target Lab Industry with PAMA Reporting, LDT Rules

TWO FEDERAL AGENCIES USED 2015 to advance their plans to increase control and oversight of the clinical lab industry. For CMS, the goal is to reduce prices the Medicare program pays for lab tests. For the FDA, it is to regulate LDTs.

CMS is acting under the mandate of the Protecting Access to Medicare Act (PAMA) of 2014. One section of the law calls for CMS to gather lab price market data in 2016, then use this data to set Part B Clinical Laboratory Test fees for 2017.

The federal agency released its proposed rule on September 25. The comment period ended in late November. The lab industry is closely watching to see what CMS will do next to issue the final rule. CMS further stated that it projected cost reductions of $5 billion over 10 years from implementation of this mandate. *(See TDR, October 5, 2015.)*

For its part, the FDA released its draft guidance for laboratory-developed tests (LDTs) in 2014. However, throughout 2015, there was plenty of action on this subject. The FDA conducted industry forums. It also testified at Congressional hearings this fall about how LDTs should be regulated.

Every lab will feel the impact of both regulatory initiatives as they are implemented. That is why this story is the most significant one of 2015 for the lab industry. The two regulatory programs will mean less revenue for labs and increased costs to comply with both proposals.

2015 TOP TEN 2

Payers Get Tougher with Lab Audits, Genetic Test Coverage Decisions

LAB EXECUTIVES WILL PROBABLY LOOK BACK upon 2015 and recognize that this is the year when government and private payers embraced a "get tough" attitude toward the lab test industry.

Audits of clinical laboratories got tougher, including some payers asking audited labs to document that they were billing and collecting amounts patients owed. Provider networks continued to narrow as health insurers worked to exclude higher-priced labs. *(See TDRs, May 11 and August 24, 2015.)*

Reimbursement for lab tests continued to shrink, particularly for new molecular diagnostic assays and genetic tests. Similarly, labs introducing new lab tests found it much more difficult to get a favorable decision to cover.

Many lab executives say they cannot remember a tougher year than 2015 for negotiating managed care contracts and obtaining favorable coverage decisions for new tests, particularly for molecular and genetic tests.

Experts say that this is the new reality in healthcare. The Medicare program struggles to balance its finances in the face of ongoing increases in the demand for all healthcare services, including lab testing. Private health insurers believe the skyrocketing number of claims for new genetic tests to be financially unsustainable. This is why they consider one solution to this problem is simply not to cover most new genetic tests. For these reasons, why lab executives should consider 2015 to be the "new normal" in payer contracting.

2015 TOP TEN 3

Immense Scale of Lab Fraud, Abuse Revealed in HDL, Millennium Cases

FRAUD AND ABUSE by a substantial number of laboratory organizations has been happening and has gone unnoticed by most hospital lab administrators—unless their outreach lab found itself competing against one or more of these labs willing to push federal and state compliance boundaries.

Did you know that federal prosecutors claim that just two lab companies used false claims to be paid almost $1 billion by Medicare and Tricare during the period 2008 through 2015? This is lab fraud on an immense scale.

Defendants in these two whistleblower cases were **Health Diagnostics Laboratories** of Richmond, Virginia, and **Millennium Health** of San Diego, California. Each lab company agreed to settle these charges and pay penalties during 2015, while not admitting guilt. *(See TDRs, September 14 and November 16, 2015.)*

There is market evidence to indicate that these two cases are simply the tip of the iceberg and that fraud and abuse is extensive, particularly in the lab testing sectors of toxicology/pain management and some specialty lab testing.

Private health insurers are waking up to this fraud and abuse. HDL found itself sued by both **Aetna** and **Cigna**. The two insurers want to recover the money they paid HDL from claims that they say, in court documents, violate their contracts with HDL.

This is why, for 2015, payers are getting tougher on labs. Audits of lab test claims are more rigorous, even as payers get tougher on out-of-network billing and coverage of new proprietary lab tests.

2015 TOP TEN 4

'Lab Test Benefit Management' Launches at UnitedHealth, BC of SC

DURING 2015, TWO MAJOR HEALTH INSURERS implemented different approaches to managing the utilization of laboratory tests by ordering physicians. This marks the formal launch of the era of "laboratory test benefit management programs."

Similar to pharmacy benefit management, a lab test benefit management company wants to deliver two benefits to payers. One, it uses algorithms developed from evidence-based medicine to preauthorize designated tests when a physician places an order. Two, on behalf of the payer, it manages a network of clinical labs that meet criteria for patient access, quality and price.

In April, **UnitedHealthcare** launched full implementation of its laboratory benefit management program, which is managed by **BeaconLBS**, a division of **Laboratory Corporation of America**. *(See TDRs, July 21, 2014 and April 20, 2015.)*

Last month, **Blue Cross Blue Shield of South Carolina** began its own lab test benefit management program administered by **Avalon Healthcare Solutions**. *(See TDR, November 16, 2015.)*

Two factors motivate payers to manage lab test utilization. One is how the growing number of molecular and genetic tests—many lacking data to support their clinical value—overwhelms payers. The second factor is that insurers are responding to the escalating amount of fraud by certain lab companies in certain sectors of

2015 TOP TEN 5

Health Insurers Seek to Consolidate: Aetna Buys Humana, Anthem Buys Cigna

IT FINALLY HAPPENED THIS YEAR! The nation's biggest health insurers moved to swallow less-big national health insurance companies as the consolidation of the health insurance industry took an unwelcome turn for labs and pathology groups.

Aetna, Inc., started this latest round of consolidation on July 3 by announcing an agreement to buy **Humana** for $37 billion. Then, just 21 days later, **Anthem** said it would acquire **Cigna** for $48 billion.

Both deals must first clear regulatory reviews before they can close. Antitrust regulators and Congress have expressed concerns about these acquisitions. Should both companies survive these reviews and go to a closing, the result will be that, between them, Aetna and Anthem would provide medical insurance to about 73 million beneficiaries.

This development is inauspicious for hospital lab outreach programs, community labs, and independent lab companies. That's because the larger health insurers prefer to contract with the two national lab companies to obtain the deeply-discounted lab prices these labs offer.

Wall Street analysts predict that more acquisitions of health insurers will take place. This will further concentrate market share among the handful of super-sized health insurance companies that survive this process.

One consequence of further payer consolidation is that, from 2015 forward, it will be increasingly difficult for regional and community labs to negotiate favorable managed care contracts with the handful of super-sized health insurers that emerge from this current round of consolidation.

2015 TOP TEN 6

Labs Step Up Efforts to Help Docs Utilize Lab Tests More Efficiently

DURING THE YEAR, more labs than ever got serious about helping physicians and their parent hospitals improve the utilization of lab tests.

In fact, 2015 is the year that it became common to find lab test utilization as a top priority in the clinical strategies of labs throughout the United States. Labs are spending money to expand their capabilities to help physicians improve how they utilize lab tests.

Leading the way on improving lab test utilization are labs in major health systems. At **Cleveland Clinic**, pathologist Gary Procop, MD, spearheads a multi-year effort to improve lab test utilization. Five related initiatives have produced more than $2 million in savings in this ongoing lab test utilization effort. *(See TDR, June 1, 2015.)*

It is a similar story at **Henry Ford Health System** in Detroit, where the lab team has developed 10 ways to add value by improving how physicians use lab tests. These 10 ways range from selecting the right diagnostic technology to reduce inpatient length of stay to decreasing unintended operating room testing. *(See TDRs, August 24 and October 5, 2015.)*

Surging interest in lab test utilization during 2015 comes ahead of the long-predicted end of fee-for-service payment for lab tests. That is why it is a timely strategy that positions labs to contribute value.

2015 TOP TEN 7

Innovative Labs Demonstrate Effective Role of Genetic Testing

THIS WAS THE YEAR when compelling evidence emerged that genetic testing contributes to improved diagnostic accuracy and a more informed choice of the best therapies.

Across the nation, childrens hospitals are among the leading innovators in the use of genetic tests to improve patient outcomes. This is true of **Seattle Children's Hospital**, where pathologists have become more closely engaged with physicians to help them select the genetic tests that are the most appropriate, as well as interpret the results to determine the most effective therapy for patients.

This value added lab service was so successful that the lab team created a service called PLUGS (Pediatric Laboratory Utilization Guidance Services) that is used by more than 30 hospitals around the United States. This program improves physicians' utilization of genetic tests while reducing the overall cost of this testing. *(See TDR, April 20, 2015.)*

Another example of progress in using genetic tests comes from **Mayo Clinic**. In support of pharmacogenomic testing, Mayo conducted a study of five genes associated with drug metabolization in 1,000 patients.

The study revealed that only 1% of the study participants had no variants in all five of the genes that were tested. This information is being used to advance patient care at Mayo Clinic. *(See TDR, June 22, 2015.)*

2015 TOP TEN 8

Next-Gen Gene Sequencing Moves Swiftly To Establish Clinical Value

NEXT-GENERATION GENE SEQUENCING proved to be the explosive trend during 2015. Not only did a large number of new lab testing companies enter the market, but a growing number of labs in academic centers and tertiary care hospitals found it feasible to acquire gene sequencing equipment and expertise and offer relevant tests for their client physicians.

How explosive is this growth? One company tracking the prices of genetic tests tells THE DARK REPORT that there are at least 60,000 unique genetic tests available for purchase from about 300 labs!

But what matters more than the increase in the total number of unique genetic tests being offered for clinical testing purposes is the ability of some of these tests to deliver improved diagnostic accuracy, guide the selection of therapy, and contribute to improved patient outcomes.

Sequencing exomes for clinical purposes is one good example. Over the past 18 months, several studies published in the *Journal of the American Medical Association* and other journals have documented the clinical value of exome sequencing for selected patients.

Another development during 2015 is that, because it is ever-cheaper, faster, and more accurate to use next-generation gene sequencing for clinical purposes, more patients are being tested. Next-gen gene sequencing represents the perfect opportunity for pathologists and PhDs to deliver more value—while improving patient care and leading the transition to precision medicine and personalized care.

2015 TOP TEN 9

Consolidation Continues to Swallow Private Practice Pathology Groups

THROUGHOUT THE YEAR and in most regions of the United States, smaller pathology group practices quietly gave up their independence by opting to sell, merge, or even become employees of the hospital or health system they served.

This consolidation of the anatomic pathology profession on a large scale is hidden from public view. That's because many of these sales, mergers, or conversions to employee status are unpublicized and involve groups of just two to five pathologists.

Among the consistent buyers of pathology group practices are **Laboratory Corporation of America**, **Quest Diagnostics Incorporated**, and **Aurora Diagnostics**. Many of their pathology group acquisitions are unannounced, as the public lab companies consider them to be immaterial for investor disclosure.

Two recent examples of larger pathology groups giving up their independence are: 1) the sale of **Consultants in Laboratory Medicine of Toledo** (16 pathologists) to Aurora Diagnostics on October 29; and, 2) the pending sale of **Pathology Inc.** of Torrance, California (16 pathologists) to LabCorp. *(See TDR, December 7, 2015.)*

Consolidation of pathology groups does not mean fewer pathologists are working. Demand for experienced pathologists is strong. Consolidation means that fewer pathologists are practicing as partners or owners of their own groups.

2015 TOP TEN 10

Theranos Starts Year as Superstar, Ends 2015 Under Intense Scrutiny

NO LAB COMPANY HAS EVER CAPTURED the attention of pathologists, lab executives, and hospital/health system administrators the way **Theranos** has. But 2015 was the year that this lab company demonstrated the truth of the adage that, "what goes up, must come down."

Theranos went "up" in 2013 when it was the subject of a complimentary profile in *The Wall Street Journal*. In the story, Theranos said it had an agreement with **Walgreens** to put its proprietary lab testing technology into Walgreens' 8,400 pharmacies nationwide. Theranos suddenly had national media attention.

The "down" came in October 2015 and the irony is that it was *The Wall Street Journal* that published an exposé about the lab company's problems on several fronts, including the allegation that Theranos had ceased using its fingerstick collection method for all but a handful of the clinical tests it offers to patients. *(See TDRs, April 20 and October 26, 2015.)*

Another news story disclosed that, based on an agreement it had with Theranos, **Safeway** had spent $350 million to build blood collection and blood test centers in 800 of its grocery stores. According to the news story, Theranos failed to deliver lab collection and lab test services to these Safeway stores.

Theranos has responded to these disclosures and posted statements about these matters on its website. It continues to conduct business and offer clinical lab testing services in Palo Alto, California, Phoenix, Arizona, and Harrisburg, Pennsylvania.

Labs Can Earn Revenue Through Data Analytics

By working with a healthcare data integrator, labs have an opportunity to be paid for lab data

CEO SUMMARY: There is a new buyer for lab test data, creating an opportunity for labs to build a new revenue stream. Medivo, Inc., of New York, describes itself as a healthcare data analytics company whose mission is to unlock the power of lab data to improve health. It works with clinical labs and pathology groups to de-identify and integrate lab test data. Then, in a healthcare "big data" effort, Medivo does advanced analytics in collaboration with client pharma companies and health plans.

CLINICAL LABORATORIES ARE SITTING on a vast reservoir of useful, marketable data. They have a problem finding a way to properly package this information, then sell it to an interested buyer.

"There is tremendous value in lab test data because pharmaceutical companies and health plans are interested in using insights or intelligence derived from the data to improve healthcare quality, patient outcomes, and reduce costs," stated Jason Bhan, MD, the Executive Vice President and Chief Medical Officer of Medivo, a healthcare data analytics company.

Medivo works with labs to de-identify and analyze lab test data to develop solutions that improve patient care. In a recent press release, Medivo stated that it has "access to over 150M patients through its nationwide network of partner labs."

By creating a marketplace for advanced analytics solutions based on lab data, Medivo is putting buyers—pharma companies and health plans—together with sellers—clinical laboratories. What Medivo does is not something any clinical lab can do by itself, at least not yet and not easily.

"Any individual provider of clinical data has a difficult time in the market. whether it is medical labs or someone selling data from electronic medical records," explained Bhan. "Because a single provider only has a small piece of the pie, it can't provide enough value.

Negotiating for Value

"This problem for individual labs is our opportunity," he continued. "We work with many labs to de-identify and aggregate their data specifically so it can be analyzed and commercialized. That makes it both viable and desirable in the pharmaceutical market, for example.

"Without these capabilities and our ability to aggregate this clinical information into bigger pools of data, an individual lab usually can't sell its data directly into the pharma market," he added.

"But once we have de-identified and aggregated this data, we provide longitudinal insights that allow us to negotiate at the value level," noted Bhan. "In this way, we are opening up a new market for lab data, which all labs already have on hand.

They simply need a way to extract additional value from it."

"For individual labs, extracting value is difficult because even the two biggest labs in the United States have data from only 25% of the healthcare market," he said. "If there are 6,000 labs nationwide, that's just too many small pieces of the pie to make a difference, but together it is an opportunity for the lab industry to benefit as a whole.

Data for Cost Control

"Pharma companies are looking for data that covers 50% to 60% of the healthcare market and they do that by putting the data sets they have together with other sources, including lab data," Bhan said.

"Now here's the fascinating part of the story for labs," he added. "Clinical labs already possess data that have substantial value for pharma companies. The data with the most value to pharma tend to be that which has the most value in the healthcare system. Oncology and molecular diagnostics are good examples because cancer is expensive to treat and molecular diagnostics are high-cost tests.

"Any high-cost test, drug, or treatment that tends to drive up the overall cost of care is a target for better utilization in the healthcare system," said Bhan. "That's because improved utilization of such tests, prescription drugs, and treatments have the potential to save the most for pharma and payers.

Market For Clinical Data

"But the market for clinical data is not limited to high-cost care," he added. "There are many diseases, such as diabetes and high cholesterol, that drive up healthcare costs and therefore there is interest among pharma companies and health plans for data on these patients. Pharma companies also are interested in data from chemistries, such as hemoglobin A1C tests, and uric acid tests.

Clinical Data Integrator Can Guide Patient Care

ONE EARLY EXAMPLE of using big data to improve patient care is happening at Medivo, a healthcare data analytics company. It uses de-identified data from many sources, including clinical laboratories and anatomic pathology groups, to identify opportunities to help clinicians deliver better patient care.

"One of the best examples we have involves patients with chronic myeloid leukemia, or CML," stated Jason Bhan, MD, Executive Vice President and Chief Medical Officer of Medivo. "Patients with CML should be tested quarterly to monitor the progression of the illness and to assess how well the patients are doing with therapy.

"We look through large data sets from some commercial labs and specialty labs to evaluate the de-identified data while looking for patients who exhibit certain patterns in testing," he added. "We find, for example, that many patients are under-tested for BCR/ABL, which is the biomarker for CML. From there, we could identify the physicians who were doing the under-testing. Those doctors then can be targeted for education.

"To date, our data has allowed us to identify 660 patients who had been in remission but were no longer in remission," Bhan continued. "So, we followed those patients over time with our lab test data to find ways to help their physicians get those patients back to remission again by switching their therapy.

"Those 660 patients show why pharmaceutical companies and treating physicians care about timely and appropriate lab testing," he stated. "They understand that regular testing of such patients allows physicians to identify which patients need a change in therapy sooner. This can involve an increase or decrease in therapy, along with identifying which patients need therapy restarted or switched."

"One area currently getting more attention is anatomic pathology," observed Bhan. "At the moment, the highest interest is in the early stages of disease, such as data from biopsies. When a lab has biopsy data, that can usually be the first clues that a patient has a disease. Pharma and health plans are interested in that data because generally, the earlier such a disease is diagnosed, the better the outcome for the patient.

"In cases where we have assembled sufficient sets of clinical data, we've seen that pharma and health plans are interested in value-based pricing because they are moving away from fee for service," he commented. "The value of such clinical data is substantial. This allows us to discuss with the health insurers and pharma companies how this will help them control costs while improving patient outcomes."

Clinical laboratories and pathology groups handling almost any volume of lab specimens will be interested to learn that their lab test data can be used to generate a new source of revenue. "Medivo has developed multiple ways to pay those labs that supply lab test data, one of which is revenue sharing. With revenue sharing, a percentage of the value of that deal goes back to the participating labs."

Fully-Encrypted, De-Identified

To assist labs with their data strategy, Medivo uses Opal, which is its proprietary de-identification software. "We provide this solution to our lab partners," Bhan said. "Each of our lab clients will put HIPAA data into Opal, and out will come fully-encrypted de-identified data. That data then is transferred to us in a secure manner.

"The de-identification technology is important because we can use the software with different types of data sources, then marry that data together," he noted. "Use of the same de-identification technology on all these data sets has a big benefit. It allows us to put together complete pictures of patients—even though those patients may have bounced from one clinical lab to another and from one hospital or physician's office to another. Without the ability to combine data from those different sources, the data would otherwise be in silos at each of those sites.

Analyzing Patient Care

"The idea is to be able to look at longitudinal patient data even though it's de-identified." stated Bhan. "By looking at longitudinal data, pharma companies and payers can piece together a patient's journey across multiple labs, multiple institutions, and multiple data sets. Then they layer it all together to view the patient's journey."

Anne Bentley, Medivo's Chief Marketing Officer, added that pharmaceutical companies have been using anonymized patient level data—typically claims and prescription data—for many years. "As an industry, pharma has used this data routinely over the years. It is now in their DNA to want to look at data longitudinally.

"If the data is incomplete in any way, pharma companies want to 'fill the gaps,' so to speak, and lab data can address that need," she continued. "And since lab data is often available earlier in the patient journey, it is of immense value to pharma and health plans."

"One challenge any data analytics company faces is volume," emphasized Bhan. "The more data you have, the more powerful analyses you can do. It also means that the data mining produces predictive analyses that are more powerful."

Bhan concluded by inviting labs to consider partnering with Medivo. "Any lab interested in realizing the full value of their data assets and preventing their data from being commoditized should consider working with us," he said. "Today, we have collaborations with labs that give us access to the lab data of 150 million patients.

Data Analysis Licensing Agreement for Lab Data Creates Opportunity for New Revenue Stream

ONE MAJOR LAB COMPANY NOTICED how Medivo Inc. was helping clinical laboratories and pathology groups generate new streams of revenue from de-identified lab test data. Last month, Medivo signed a nonexclusive licensing agreement with **Quest Diagnostics Incorporated.**

Founded in 2010, Medivo focuses on mining clinical laboratory data to develop advanced analytics solutions that help pharmaceutical companies and health plans manage care more effectively.

"Under this new agreement, Medivo will analyze Quest's de-identified patient data from 20 billion lab test results to identify patterns in test ordering and result values that indicate the need for intervention with patients or the need for physician education," stated Jason Bhan, MD, Executive Vice President and Chief Medical Officer of Medivo. "Data analytics helps labs to locate and quantify underutilization and opportunities for add-on testing.

"By analyzing lab test results, for example, we can identify when patients fit a certain profile," he explained. "Then we can notify our pharmaceutical partners that a physician practice has a number of patients who match a specific profile," he said. "For example, some patients may have chronically high levels of cholesterol, or the hemoglobin A1C values may be too high.

"Having this information gives our partners an opportunity to educate these physicians about the benefits of using the appropriate therapy before the physician makes a treatment decision," Bhan added. "In this way, our pharmaceutical company clients might bring a therapy to the attention of the clinician that may be more suitable than what that physician would typically prescribe.

"Here's how it works," he continued. "Medivo's clinical and data science teams have developed nearly 500 proprietary patient algorithms based on recommended clinical guidelines for certain conditions. By following these guidelines, Medivo can identify patients who fit certain profiles based on their lab test results.

"From there, we can match these de-identified patients with the medical practice where they get treatment," noted Bhan. "Then, manufacturers of these new medications can educate the physicians about their treatment options for these patients.

"Our analysis of the data also is important for physicians, health plans, and anyone interested in identifying gaps in care," emphasized Bhan. "When the data shows which physicians are responsible for any gaps in care, we report that information to our lab partners and pharmaceutical clients who have developed many different kinds of educational programs and outreach efforts to explain to physicians the need for more appropriate testing according to clinical guidelines. In fact, most pharma companies have whole divisions focused on developing educational tools aimed at ensuring appropriate utilization of lab testing."

"As pathologists and clinical laboratory scientists know, in the world of healthcare big data, the larger the set of data available for analysis, the more powerful our lab data discoveries can be," commented Bhan. "This is why pooling ever-larger quantities of lab data can create even greater value for the lab industry as a whole."

Clinical labs and pathology groups looking for new sources of revenue should investigate this opportunity to sell lab data. The agreement between Medivo and Quest Diagnostics is evidence that Quest saw financial benefit from selling its data. TDR

—Joseph Burns

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Regulatory Update

Letter from Congress to CMS Asks for Delay in PAMA Reporting

Senators, Representatives request CMS engage in 'constructive dialogue' with lab stakeholders

CLINICAL LABORATORY ASSOCIATIONS are using a letter-writing campaign to members of Congress as a last-minute Hail Mary attempt to head off the controversial lab price market reporting rule that CMS intends to implement after January 1.

Both Democrats and Republicans in the U.S. House of Representatives and the U.S. Senate have signed a letter to the acting administrator of the federal **Centers for Medicare & Medicaid Services** asking for a delay of the rules to implement the Protecting Access to Medicare Act.

Copies of the letter, dated December 14, circulated in both houses of Congress. The letter asks CMS Acting Administrator Andrew Slavitt to delay implementing the Medicare Clinical Diagnostic Laboratory Tests Payment System Proposed Rule. CMS published the proposed rule in the *Federal Register* on October 1.

Fears of Skewed Data

Alan Mertz, President of the **American Clinical Laboratory Association**, said, "This Dear Colleague letter vigorously illustrates that the proposed timeline for reporting data and pricing will result in skewed data and Medicare rates that do not reflect the market."

The letters signed by senators and representatives explain the biggest problems labs have with PAMA since the Act was signed into law in 2014. In the letter, members of Congress say they are concerned about several specific provisions of the proposed rule. First, the letter says CMS should, "…provide clinical laboratories with sufficient time to implement these important changes, and preserve market competition to ensure continued access to laboratory services."

The timeline calls for CMS to set rates for clinical laboratory tests starting January 1, 2017, based on lab-pricing data to be collected starting January 1, 2016. Clinical labs have no idea how to comply with CMS' data collection system as outlined in the Medicare Clinical Diagnostic Laboratory Tests Payment System Proposed Rule, published October 1, 2015. Under the proposal, some labs are prohibited from participating in the reporting process CMS recommends, the letter said.

"We are deeply concerned that this prohibition will skew market data, resulting in Medicare rates that are not reflective of true market prices," the letter said.

Another concern involved CMS' definition of a new category of tests—advanced diagnostic laboratory tests (ADLTs). Language in the PAMA statute says that an ADLT must analyze multiple biomarkers of DNA, RNA, and proteins. But the CMS definition leaves proteins out of the definition, a critical factor because pathologists look for protein-based diagnostic markers to help them make clinical decisions regarding patient care, the letter says. TDR

—Joseph Burns

FDA Official Makes Case In Favor of LDT Guidance

Despite criticism from clinical labs, he says FDA will continue to pursue regulation of LDTs

CEO SUMMARY: Forty years ago, pathologists in hospital and academic labs worked closely with treating physicians to produce LDTs for discrete clinical cases. Seeing that, the FDA decided not to regulate those tests, an FDA official said. Over time, however, use of LDTs became a serious concern when labs developing LDTs were no longer involved with their use for individual clinical cases. These labs marketed their LDTs nationwide and made claims about their validity that were unsupported by evidence, the official said.

IN RECENT COMMENTS, AN FDA OFFICIAL confirmed two points. First, the federal agency will continue to promote the guidance it proposed last year for labs offering laboratory-developed tests. Second, the FDA recognizes that it is possible that a lawsuit may result from clinical labs wanting to challenge the FDA guidance for LDTs.

These comments were made by Alberto Gutierrez, PhD, Director of the FDA's Office of In Vitro Diagnostics and Radiological Health. He was one of four speakers who participated in a webinar sponsored by the **Harvard T.H. Chan School of Public Health** and *STAT News*.

FDA Oversight Of LDTs

Separately from this webinar appearance, the FDA gave lab executives and pathologists an idea of the evidence that it will put forward to demonstrate that LDTs can harm patients. On November 16, prior to a Congressional hearing on LDTs, the FDA issued a 39-page FDA report, "The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies." The report said that some "LDTs provided information with no proven relevance to the disease or condition for which they are intended for use, while still others are linked to treatments based on disproven scientific concepts. In addition to patient harm, inaccurate or unreliable tests can be costly to society."

In response to the release of this document, the **Association for Molecular Pathology** said only a few of the 20 LDTs in the FDA's report could cause harm that FDA oversight might have prevented.

The examples were outlier assays; a problem with treating physicians using treatments outside accepted medical practice; analytical errors, which both FDA and CMS acknowledge are best addressed by CLIA; or failure of treating physicians to follow up a screening test with a diagnostic confirmation test, declared AMP. Along with AMP, other clinical lab associations have challenged the FDA's authority to regulate LDTs as proposed.

But in remarks during the webinar on December 11, Gutierrez explained much

about the agency's thinking on LDTs. He predicted that the FDA will proceed with its guidance despite the push back from clinical labs. He invited clinical labs to work with the FDA to improve its review processes.

In his remarks, Gutierrez explained that soon after the passage of the Medical Device Amendments of 1976 (MDA), the FDA reviewed the need to regulate LDTs. "Early on we made a determination that there were certain tests that were created typically in hospital and academic laboratories where the pathologist worked on the clinical case and that likely would not need our overview. And so we decided not to regulate those tests," he explained. But over time, the development, use, and spread of LDTs became a serious concern, he said.

A Shift to Widespread Use

"In the mid 1990s, the FDA saw a shift from labs becoming more of a service to providing these tests to physicians," continued Gutierrez. "With the ability to ship samples all over the country, we saw a shift of labs not being near the patient or being part of the patient treatment.

"[Along with that trend]... we also began to see where labs created one [LDT] test and marketed it all over the country with claims that were done by the company," he noted. "So the FDA began to regulate these tests in the late 1990s and it proposed several ways to move forward.

"In 2010 we said we would regulate these tests the way we regulate everything else and we put a draft proposal together in 2014," added Gutierrez. "The idea [behind the draft proposal] is to bring laboratory-developed tests on the same par, if you like, [with the way] that we regulate all other things, which is to look at premarket claims they make and determine whether they [the claims] are clinically valid or not."

During the webcast, a video was shown of a couple who had a prenatal screening test done to test for the presence of trisomies 13 and 18, which are chromosomal disorders that lead to mental retardation and birth defects. The couple became distraught after getting a false-positive result and no information about the need for follow up testing.

"The example in the clip is a good one," Gutierrez commented. "The company set up and marketed it [the LDT] really erroneously because the test is actually a very good test as a screening test and it should be a screening test. It's much better than the previous way that prenatal screening was done. But the fact is that, because of the prevalence of the disease—and no test is perfect—you are going to get false results.

"If the prevalence drops, the number of false positives is going to increase," he added. "So the fact that the company was selling this [LDT test] as extremely accurate and not telling people beforehand that when they get a positive result it was unlikely to be a positive result, particularly for trisomy 13 and trisomy 18, [is problematic].

"Those are the kind of things that we want to be able to regulate and have companies be wholly responsible for making claims that are appropriate for what they have," he said.

A Question of Authority

Asked if the FDA has the statutory or regulatory authority to regulate claims about LDTs, Gutierrez stated, "We do. If you look at the 1976 statute, it talks about the type of tests, and the type of *in vitro* reagents, and the type of things that we regulate. It does not limit us to regulating based on where they are made. So we believe we actually do [have the authority]. That's the reason we are going through a guidance process.

"The labs are fairly upset and claim that, one, we don't have the purview of the labs and, two, they say we probably should have done this through rule-making because we are imposing new regula-

FDA to Congress: Draft LDT Guidance Has a Goal to Improve Patient Safety

IN CONGRESSIONAL TESTIMONY last month, Jeffrey Shuren, MD, JD, said the FDA's effort to regulate laboratory-developed tests is driven by an effort to minimize patient harm. Shuren is the FDA's Director of the Center for Devices and Radiological Health. He addressed the House Energy and Commerce Committee's Subcommittee on Health.

Regarding LDTs, Shuren said, "The real loser here is patients. Doctors and patients don't care about who makes their test. They do care that their tests are accurate, reliable, and clinically valid."

He also acknowledged that some labs are cooperating with the FDA on its efforts to develop an oversight system for LDTs.

"Now some labs have already been working with us and we congratulate them for crossing that picket line," observed Shuren. "Our message and our invitation to the rest of the lab community is to put down the swords. For the sake of our patients, it is time to end the saber rattling and partner with us moving forward."

Shuren testified on November 16, the same day the FDA released its latest report on the need to regulate LDTs, "The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies." In that report, the agency said FDA oversight of LDTs is needed to address the following concerns:

- Lack of evidence supporting the clinical validity of tests
- Deficient adverse event reporting
- No premarket review of performance data
- Unsupported claims from manufacturers
- Inadequate labeling of tests
- Lack of transparency in how LDTs are developed
- No comprehensive list of all LDTs in use.

The FDA also is concerned about the uneven playing field in which these tests are developed. If a laboratory is developing an LDT and conducts the research needed to validate their tests and seek premarket review from the FDA, it is at an unfair disadvantage when other labs do not follow the same standards to support their claims and the safety and efficacy of their device, the report explained.

LDTs also threaten the scientific integrity of clinical trials, because clinical investigators often rely on LDTs when selecting patients for participation in trials. If the tests used to select patients are inaccurate, then the scientific conclusions derived from these trials also could be inaccurate, the FDA said.

tions on them," he continued. "As it turns out, it really was a policy decision back then [after 1976 by the FDA] and that policy decision was exploited—to a certain extent.

Guidance Is 'Best Thing'

"The FDA thinks that doing this with guidance is the best thing to do," added Gutierrez. "The reason is that things that go into law and that go into regulations are typically very difficult to change.

"LDTs are an area that will be difficult to regulate," he emphasized. "There is a broad set of tests. Some of the LDTs are very good. Some of them require a lot of expertise from the pathologists and some of them don't.

"Regulating LDTs in a way that makes sense and that does not disrupt what's going on [in labs] is going to be difficult," he acknowledged. "So doing it through guidance allows us to step into this area in a way... where a third party [the FDA] will be looking at their clinical ability." Gutierrez also added that the FDA will push for labs offering LDTs to be better with the quality systems that support the LDT results they

report... "without hopefully stopping a lot of really good work."

Asked if the FDA were concerned about labs pushing back against the FDA's efforts, possibly with a legal challenge, Gutierrez responded, "The plan is to move forward with the guidance that we're doing. Are we going to get sued? A lot of people think we might and that would obviously be problematic.

A Lack of Transparency

"We have been trying to work with the laboratory community," he continued. "In reality there have been some advances. One of things we tried to do in the mid 2000s is we identified a set of tests that we were particularly concerned with. Those were tests done with proprietary data that were not published. And we felt that an independent review would be needed for those tests."

"[Since then,] the laboratories have come around in their proposals and have made several legislative proposals to Congress," he stated. "Even the laboratories that have been most opposed to the FDA have at least understood that perhaps there are some set of tests that probably should be reviewed by the FDA.

In that respect, "we have come a long way," commented Gutierrez. "There is a consensus now that LDTs should show that they are clinically valid before they are offered and that somebody should be able to verify that."

Going Too Far?

Some labs are afraid the FDA might go too far, he added. "I understand that if the FDA overregulates [LDTs] there will be a problem," Gutierrez explained. "So we clearly have to, and we would like to, get the cooperation of laboratories because we are not going to be able to do it well unless the laboratories cooperate.

"We think we will continue down the path of our guidance though we are sure that the laboratories and Congress will continue looking at legislative proposals—in part because, if there is a lawsuit it will be somewhat uncertain what we will be able to do or not," he stated. "I do think we will move toward something that is at least more regulated."

One area of concern is whether the FDA will apply the LDT guidance retrospectively or for new tests only. "The draft guidance is a way to put a proposal on the table and get feedback," he commented. "The draft LDT guidance did apply to old tests that are out there, but we proposed a nine-year implementation [plan] so that people will have plenty of time. And that implementation will be risk-based so that the tests that are currently the highest risk would be first" and "...most LTDs would be considered moderate risk and would be [evaluated] five to nine years down the road."

Gutierrez concluded by saying the agency has been considering some of the comments labs have made on the proposed LDT guidance. "We could grandfather what's there but then shorten the implementation," he commented, citing one example. TDR

—Joseph Burns

FDA Lists 20 LDTs That It Considered Problematic

EVERY PATHOLOGIST AND LAB EXECUTIVE following the FDA's effort to regulate LDTs will find the federal agency's report, "The Public Health Evidence for FDA Oversight of Laboratory-Developed Tests: 20 Case Studies" to be informative.

The authors analyze the quality issues associated with each of the LDTs. Included is an assessment of potential patient harm, whether from issues associated with sensitivity and specificity, or from how physicians utilize the test to diagnose a patient and then determine appropriate treatment. The full report can be accessed at the FDA website or with this URL: *http://tinyurl.com/oxmrnur*.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

To advance the practice of precision medicine through better use of genetic testing, a new limited liability corporation (LLC) was formed. Participating in the LLC are **North Shore-LIJ Health System**, the nation's largest urban health system, **OPKO Health, Inc.**, a pharmaceutical company, and **GeneDx**, a division of **Bio-Reference Laboratories** (both lab businesses are owned by OPKO). "The purpose of this alliance is to advance the promise of precision medicine by providing our patients with greater access to these potentially life-saving tests, while at the same time evaluating their utility and clinical value," stated James Crawford, MD, PhD, in a press release about the collaboration. He is Chair of Pathology and Executive Director of Laboratory Services at North Shore-LIJ.

ADD TO: *North Shore-LIJ*

This unique combination of a major health system, a pharmaceutical company, and a gene testing lab company, announced on December 17, is an early example of the types of collaborative ventures that can be expected as health systems evolve into fully-integrated healthcare delivery organizations. ACOs will access expertise in genetic testing and its interpretation from expert lab test companies like GeneDx. In turn, the ACOs will provide the gene testing companies access to patients and their relevant clinical data. *(North Shore-LIJ will change its name to Northwell Health in January.)*

LAB MANAGEMENT

On December 10, **Barnabas Health** of West Orange, New Jersey, and **Quest Diagnostics Incorporated** announced an agreement that calls for Quest to manage laboratory operations for the seven hospitals operated by Barnabas Health. The press release stated that Barnabas' "patients and consumers will have expanded information connectivity options, reduced laboratory testing costs, and access to Quest's IntelliTest Analytics solution, which provides timely access to utilization insights." Quest is actively pursuing lab management agreements with hospitals throughout the United States.

TRANSITIONS

- **Abcodia Ltd.** of Cambridge, United Kingdom, announced that Richard A. Sandberg joined its board of directors. He is currently Chairman of the board at **Oxford Immunotec Global, Plc**. Sandberg founded **Dianon Systems** in 1983 and was CEO of Dianon in the early 1990s when the lab company launched the strategy of soliciting biopsies and other lab tests from specialist physicians throughout the United States.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, January 19, 2016.