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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Labs Beware! More Patients Have Higher Deductibles

ONE TREND THAT PUTS FINANCIAL PRESSURE on both clinical laboratories and pathology groups is the growing number of patients who have higher deductibles. This means labs must work harder and smarter to collect all the money that is due them from the patients they serve.

How advanced is this trend? Last fall, the **Kaiser Family Foundation** released a report noting that 2016 was the first year where 51% of workers (more than half) in a single coverage health plan must pay at least a $1,000 annual deductible. For workers at small firms (three-199 workers), this number is now 65%.

There's a similar story in the enrollment growth of high-deductible health plans (HDHPs). According to Kaiser, as of 2016, 29% of workers with insurance now have HDHPs. That number is a 50% increase from 2014, when just 20% of workers had HDHPs.

These are the market statistics that validate the reality that clinical labs and pathology groups experience daily. More of their patients have health insurance that requires them to pay substantial amounts of their lab test bills themselves, before insurance coverage kicks in. For patients in high-deductible health plans with an annual requirement of $5,000 to $10,000, that means the lab must collect 100% of the lab test bill, particularly in the first half of the year.

Labs are not the only providers struggling with the trend of higher patient deductibles. Hospitals have been hit hard by the need to collect greater amounts of money directly from patients. In a story published this month by *Modern Healthcare*, Jase DuRard, Chief Revenue Officer for revenue-cycle vendor **AccuReg** said, "About five years ago, insurers paid about 90% of hospital claims, with patients responsible for about 10%. Today, the mix is 70% by insurers and 30% patient out-of-pocket."

There will be substantial changes in the financial management of the nation's clinical labs and pathology groups when the patient-pay proportion of their revenue climbs to 30% or more, as is happening at hospitals. Among other things, it will be necessary for labs to collect payment from patients when they show up to have their specimens collected. Thus, it would be timely for all labs to develop strategies to handle collecting monies owed by patients. TDR

Konica Minolta to Pay Up to $1 Billion for Ambry

Ambry's founder had vision to offer value with full gene sequencing, genetic counselors

CEO SUMMARY: It's the second time in six years that a Japanese corporation paid a high price for a genetic testing company in the United States. Konica Minolta will purchase Ambry Genetics for $800 million at closing and $200 million upon hitting certain financial metrics. In 2011, Miraca Holdings acquired Caris Life Sciences for $725 million. Ambry Genetics has an interesting story and says its use of genetic counselors has helped it win in-network status for 97% of Americans with private health coverage.

On Wall Street, it was big news earlier this month when **Konica Minolta** said it would pay as much as $1 billion to acquire **Ambry Genetics**, a private genetic testing company in Aliso Viejo, Calif. Konica Minolta will pay $800 million and as much $200 million more based on certain financial metrics over the next two years, the companies said.

Media coverage of this acquisition emphasized the large purchase price and the fact that a Japanese company better known for making photocopiers and printers was placing a big bet to expand into clinical diagnostics.

For Konica Minolta, the acquisition is an important way to diversify beyond office equipment where revenue and profit have declined in recent years, *The New York Times* reported. The printer and copier company already has developed technology to detect cancer, using light-emitting nanoparticles to mark proteins drawn to cancer cells, the Times said.

News accounts also noted that the high price for Ambry will encourage more investment in molecular diagnostics and genetic testing.

But the news coverage missed more interesting aspects of the story behind the sale of Ambry to a large Japanese conglomerate. Ambry's success is a classic tale of the American Dream—but with a sad and ironic twist.

In 1999, Charles Dunlop raised $500,000 and founded the company. His vision was to deliver high quality germ-line genetic testing services based on the advice of genetic counselors. Since then, Ambry has performed more than 1 million genetic

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tests and identified more than 45,000 mutations in 500 different genes.

For Dunlop, the goal wasn't simply to have patients use genetic testing to learn if their genes pre-disposed them to disease. "The more important goal was to offer consumers an informed method of deciding if such testing was appropriate by basing such decisions on not just being affected with a disorder but also the history of disease among mothers, fathers, aunts, uncles, and other relatives," explained Ambry CEO Aaron Elliott, PhD.

Genetic Cause of Cancer

Post-acquisition, Ambry will keep Dunlop as an adviser and Elliott as CEO. In a cruel twist in 2014, Dunlop, age 42 at the time, learned he had stage 4 prostate cancer and identified the genetic cause of it after taking a test that Ambry offers. The cancer is in remission today, yet the experience was one reason he decided it was time to sell, Elliott said.

The fact that Dunlop had a germ-line based disease also played a role in one of the more controversial decisions the company made: Last year, Ambry made public its genetic database of anonymized patient data. It did so believing that such a resource would be useful to researchers and oncologists. *(See sidebar, page 5.)*

Another attribute of the company that is important for lab executives to understand is that Ambry will continue to focus on maintaining strong relationships with genetic counselors as a way to ensure that only appropriate genetic tests are performed for each patient, Elliott said in an interview with THE DARK REPORT.

Differentiating Its Services

"Making extensive use of genetic counselors is an important part of our business model because it helped our company offer the highest quality tests available," stated Elliott. "This helped Ambry become an in-network provider for almost 97% of Americans who have health insurance.

"Before 2013, most of our business came in via an institutional bill," he said. "The hospital or a clinician would pay Ambry for our tests. But that switched in 2013 when we offered testing for BRCA1 and BRCA2. The majority of our business is now insurance-based testing.

"Over this time, we've nurtured the relationships we have with managed care companies to help them understand the quality of our testing compared with that of other labs," he said. "Of course, the close relationships Ambry has with genetic counselors is important to insurers as well.

"We have always been a very genetic-counselor-centric company," continued Elliott. "We employ more than 100 genetic counselors at Ambry and have them in almost every department in the company, including sales support, marketing, and obviously in reporting.

In-House Swiss Army Knives

"In a sense, these genetic counselors are our Swiss Army knives. We use them for guidance and input and so it makes sense that a lot of our clients gravitate toward us because of how we rely on genetic counselors," he explained.

"That was part of the genius behind the vision Dunlop had when he founded the company," Elliott added. "He started with a small amount of money and never relied on institutional investors. The most ever raised was only $500,000.

"In biotech, it usually takes a significant investment to get up and running," he explained. "But Ambry was launched and has grown because of the capital raised mostly from Charlie's family and friends.

"In those early years, Ambry's first test was for cystic fibrosis," Elliott recounted. "At that time, there were a few hot spot panels when doctors looked at CF mutations. But Charlie's idea was not to sequence just a few mutations but to analyze the whole CFTR gene. He thought there could be cases in which people have

mutations besides the most common ones. That was his idea for the business.

"We started with Sanger sequencing for the cystic fibrosis gene and reached out to the **Cystic Fibrosis Foundation** to offer a free test to any doctor who would send a sample for testing," he recounted. "We said that first test would be free and the very next day samples started arriving. From there, the company gradually introduced new genes and added new products to the test menu and expanded from there.

CF Testing as Loss Leader

"We didn't offer free testing for long," he said. "But at that time, in the years 1999 and 2000, no one did full gene sequencing on a diagnostic level, especially for CF. But our test—with its expanded gene coverage—helped doctors diagnose more patients with greater accuracy.

"From there, the business grew through word of mouth because we had relationships with so many genetic counselors and our testing was mostly priced to be relatively affordable," recalled Elliott.

"For all those years, we didn't have any significant commercial sales effort," explained Elliott. "It was not until 2010 or 2011 when Ambry started hiring sales support staff. We still have the smallest sales force for any major diagnostic lab. We have only about 100 sales people, which is much smaller compared with our competitors.

"The next big milestone came in 2013 when the Supreme Court ruled for us in our case against Myriad," Elliott explained. "That's when the business really exploded."

In 2013, the U.S. Supreme Court ruled that Myriad Genetics' patents on the BRCA1 and BRCA2 genes were invalid, and Ambry and other labs began offering those tests.

"By that time, we offered hereditary cancer tests because there was an established market for those tests with fairly good reimbursement," he stated. "Ambry was the first company to offer hereditary cancer panels. Even before the Supreme Court ruling, we had launched these panels.

"At this time, it was well known that Ambry was getting negative samples from Myriad," Elliott added. "If a patient tested negative for BRCA1 or BRACA2, the clinician would send the sample to us so that we could test the other genes implicated in hereditary cancer for which Myriad didn't test.

Ambry Caused Controversy By Publishing Gene Database

IN MARCH 2016, AMBRY GENETICS made an unusual decision: it would make genetic-test data available to the public from 10,000 de-identified hereditary cancer patients. It did so to aid researchers looking for genes associated with various types of cancer.

For a company built on having a strong relationship with genetic counselors—it employs more than 100 of them in various roles—the move came with a downside, explained Aaron Elliott, PhD, CEO.

"We had a mixed response to our release of that data," he said. "Some large academic institutions were absolutely thrilled that we released this data. But there were others, including genetic counselors, who questioned the consent process.

"Some genetic counselors weren't happy for the simple fact that they didn't consent their patients to this specific research project," explained Elliott. "We responded with dramatic changes to our consent process. This was an important lesson for Ambry.

"We did this project—which we called AmbryShare—as a pilot," he added. "It was designed to be a gene-discovery project to help labs and researchers find new genes implicated for hereditary breast and ovarian cancer."

"After the Supreme Court decided in our favor in the case against Myriad, we added the BRCA1 and BRCA2 tests to our menu," said Elliott. "We saw an immediate increase in specimens because we had a long history with genetic counselors as having the best-quality tests. That test volume grew almost overnight.

Subsidized Testing Costs

"Over the years, of course, different companies, such as **Invitae**, have started competing with Ambry," he noted. "These companies can do that by offering low prices because they're subsidizing their costs with investor money. Many genetic testing companies lose enormous amounts of money because the price they offer may not cover all their costs.

"Ambry's viewpoint has always been quality first, which means being number one in terms of delivering accurate results," Elliott said. "That's how we've grown our business.

"Today, we run a bit more than 100,000 tests each a year on the hereditary cancer side," he added. "When we add in some of the other tests we run, we might do about 150,000 samples a year. Over the past two to three years, that test volume has been very close to the highest it's ever been."

Currently, Ambry employs a staff of more than 700 and that number is down from about 800 two months ago. "We've automated many processes and consolidated to eliminate redundancies and some departments," Elliott explained.

Lessons Learned

Looking back over the company's history, Elliott does not believe it would be possible to start a company like Ambry today. The marketplace is too segmented and unforgiving.

"The genetic testing market today is a much different than it was in 1999," he conceded. "The competition is so stiff today. Even five years ago you didn't have these low-cost providers who can do testing more cheaply because they use the latest generation of technology. The barrier to entry has gone way down and investor money has flooded in to build labs because of the potential growth in personalized medicine.

"On top of that, insurance companies are seeking value-based analysis for genetic testing, which to them seems to mean low cost," he added. "Payers all want to control the cost of genetic testing and one way they do that is to use low-cost providers as leverage to try to bring costs down at labs like ours. Our response is to demonstrate and document that we offer better quality and high accuracy. We built our reputation on those two factors and they have sustained us so far."

Secrets of Ambry's Success

Wall Street investors are taking the sale of Ambry Genetics to Konica Minolta for a price of as much as $1 billion as affirmation that the market for molecular and genetic testing companies continues to be robust. Overall, that will encourage more investment in genetic testing companies.

But what often gets overlooked are the unique vision and ethics of the entrepreneurs who start some of these genetic testing companies. In the case of Ambry, founder Charles Dunlop recognized the clinical value of two things. The first was emphasizing the role of genetic counselors to ensure the right test was ordered and then both the physician and the patient understood how to evaluate the results when making treatment decisions.

Second was to sequence the entire gene relevant to the patient and the disease. This incurred a higher cost compared to competing labs, but it gave the ordering physicians a richer, better answer—and they noticed. TDR

—Joseph Burns

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USC's Clive Taylor, MD, Talks Digital Path, WSI

Noted pathologist shares insights, predictions into how this technology may disrupt pathology

CEO SUMMARY: The FDA's clearance of the first digital pathology system for use in primary diagnosis will be a disruptive force for pathologists in the coming years. At the University of Southern California Keck School of Medicine, pathologist Clive Taylor, MD, predicts that the benefits of whole slide imaging and digital pathology will enable pathologists to cut the time to diagnosis and allow them to offer enhanced diagnostic services that contribute to improved patient care.

In the wake of the FDA's clearance of whole slide imaging for primary diagnosis of biopsied tissue, digital pathology has become a key strategic issue for all pathologists. The question is no longer "should we buy a digital pathology system?" Rather, it is "When should we invest in digital pathology and whole slide imaging?"

To help pathologists answer this question, The Dark Report turned to Clive Taylor, MD, PhD, a professor of pathology at the **Keck School of Medicine at the University of Southern California** (where he served as Chair of Pathology from 1984 to 2009).

Taylor is one of the esteemed leaders in the field, not just in the United States, but around the world. He offered keen insights into how digital pathology can be disruptive, along with several bold predictions of interest to pathologists in academic or community settings.

"April's FDA clearance of the **Philips** IntelliSite Pathology Solution (PIPS) for primary diagnosis is significant for many reasons," commented Taylor. "PIPS is the first whole slide imaging (WSI) system to pass the FDA's regulatory hurdles for reviewing and interpreting digital pathology slides prepared from biopsied and resected tissue.

"The FDA's clearance of this system for primary diagnosis is huge," he continued. "It could have been any vendor, but Philips got there first, and just the fact that it's now approved will break a log jam.

Digital Scanners

"I say that because digital slide scanners in many pathology departments around the country are used secondarily," he explained. "For example, a pathologist will look at a glass biopsy slide today and think, 'I should scan this to get a score, or an accurate count, or to send it to a colleague in Washington or London or some place.' In that sense, pathology labs are using whole slide imaging for secondary purposes.

"The FDA clearance of whole slide imaging for primary diagnostics will foster changes in anatomic pathology departments that will improve the accuracy and

speed of diagnosis and drastically reduce the time it takes to get second opinions and to reach a primary diagnosis," Taylor predicted.

"Now that whole slide images can be used for primary diagnosis, we will start to integrate them into the diagnostic process, beginning with conferences and shared consultations with colleagues," he noted. "In some pathology departments, in less than three years we can expect to see digital pathology systems used for most primary diagnosis. But it may take as long as 10 or more years in other pathology departments.

➤More Images, Fewer Slides

"Eventually, histology labs will send only digital files (WSIs) to pathologists, and glass slides will no longer be sent unless pathologists ask for them specifically—usually when they have a case that is difficult to interpret and they seek the comfort of glass slides to which they are accustomed," offered Taylor. "But as digital experience grows, recourse to glass slides will diminish, because much more can be achieved with a digital image.


Clive Taylor

➤Now that whole slide images can be used for primary diagnosis, we will start to integrate them into the diagnostic process.

"Having said that, digital imaging will definitely produce some workflow changes very soon," Taylor added. "Right now, everything in anatomic pathology departments hinges on the histology lab which starts its work early in the morning. That's when it removes specimens from the overnight batch processors and begins slide cutting and staining runs.

"Only after all batches are complete does the histology lab release the glass slides to the pathologists, who may be in a distant office or even a different building," he said. "The pathologists can't do their daily sign-outs until the slides arrive. And they usually arrive in batches of 100 or more slides.

"There will be significant workflow advantages from switching to a digital system," he stated. "As glass slides come off the staining runs, they will feed into the scanner and the barcode will send the whole slide images immediately to the appropriate pathologist. As that happens, the pathologist will be notified on his or her laptop, phone, or desktop that there are cases to review.

"This will dramatically cut the time that pathologists wait for batches of slides," said Taylor. "Once a pathology group goes digital, it can feed glass slides into the scanner immediately after the staining is finished in a continuous production mode.

"Case-by-case, as the whole slide images emerge from the scanner, barcoding lab systems will allow them to be distributed automatically to the specified pathologists on service or to the subspecialist for each particular case," added Taylor. "The system will ping the pathologist that a case is ready for sign out. Not having to wait for the whole batch will speed things up significantly.

"Another benefit of WSI will be the ability to use computer-guided algorithms. Because we'll be using digital images and not glass slides, pathologists can get assisted diagnosis easily," he explained. "This already happens in radiology where a CT scan is computer reviewed against previous scans. That computer review draws the radiologist's attention to certain areas. WSIs will allow a similar thing to happen in pathology."

Taylor has another unusual prediction. He believes the profession of pathology will benefit from an explosion of apps. "Think of how apps have been developed for the iPhone or other smart phones," he observed.

"This spring, Silicon Valley celebrated the 10th birthday of the iPhone and it

struck me that just 10 years ago, the iPhone had about five or six apps when it came out," he stated. "Now there are 2 million.

Millions of Digital Path Apps?

"That's what happens when you give smart people digital files with which to work," continued Taylor. "To be sure, there won't be 2 million apps in pathology but I would bet that, within five years, there'll be 1,000.

"The reason I say that is because digital files lend themselves to so much analysis," he added. "For example, think about how we use Google Maps to find restaurants in an unfamiliar town. We will apply similar technology to digital slides, allowing pathologists to instruct systems to show us the nearest cancer cells in an unknown tissue section. In fact, this technology already exists through machine learning. It will just take time for it to become a normal part of pathology practice.

"Another way to look at what will happen is to examine how digital imaging changed radiology," Taylor suggested. "Radiology had intrinsic advantages and lots of cost savings by doing away with hard radiology films and the use of silver salts.

More Efficiency Coming

"Subsequently, time and motion studies showed that fewer radiologists were doing the work that more radiologists did previously," observed Taylor. "The workload has gone up, but the number of radiologists has not. Some say that five radiologists now do what 6 or 7 did previously. I'm sure a similar trend will happen in pathology.

"In most pathology practices today, we spend a substantial amount of time sorting, delivering, and looking for glass slides and the matching paperwork," Taylor said. "Lab information systems already exist such that when they are applied to digital WSI files this problem will almost entirely disappear.

"Another problem that digital files will solve for us is the time it takes to get an internal second opinion with glass slides," he added. "To share a case today, you have to find your colleague, walk down the hallway, show the slide, wait while your colleague looks at it, and then walk back and change the report. That's 20 minutes gone. Digitally you could do the whole secondary review in 5 minutes.

"Also it is generally agreed that sharing a slide improves the quality of the diagnostic process," he said. "If you want to show an image to a subspecialist in your department, you would be able to do so with the press of a button.


Clive Taylor

I believe that digital pathology and whole slide imaging will improve the accuracy and speed of diagnosis.

"The same will be true for the ability to share images with an expert at the **National Cancer Institute**, for example," Taylor added. "Getting a review from someone at NCI could take a week or more now, but it might take only minutes in the coming years.

"For all these reasons, I believe digital pathology and whole slide imaging will improve the accuracy and speed of diagnosis," he concluded. "All of those things will change the practice of pathology.

"It will be the biggest change in 180 years, since the introduction of the microscope itself," Taylor predicted. "And the cost savings will have to come from improvements in logistics and productivity of technologists and pathologists because, unlike in radiology, we won't save money on silver salts used in developing radiology film." TDR

—Joseph Burns

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CEO SUMMARY: In five months, Medicare officials will implement a new Part B clinical laboratory fee schedule based on private payer lab price data submitted by certain medical laboratories required to report that data. At this year's Executive War College, the CEO of XIFIN, Inc., reported on her company's analysis of the payer price data its lab clients submitted, along with a discussion about the flaws in the PAMA final rule. The analysis shows why hospital lab price data is essential to an accurate market price study.

Will CMS use flawed data to set Medicare fees?

Hospital Lab Data Essential For CMS Market Price Study

SIGNIFICANT CHANGES ARE COMING to Medicare Part B clinical laboratory payment rates as the federal **Centers for Medicare and Medicaid Services** prepares to implement, on Jan. 1, market-based pricing under the Protecting Access to Medicare Act (PAMA) of 2014.

"Labs should be aware that the Medicare program's effort to implement a market-based pricing system will come just before many lab companies will be required to change their systems for recognizing revenue to meet the requirements of the Financial Accounting Standards Board's Rule 606–Revenue Recognition Standard," stated Lâle White. "It may turn out that Medicare's market-based pricing system may not be based on market rates after all."

White, is the Founder and CEO of **XIFIN, Inc.**, a company that optimizes laboratory billing, collection, and revenue cycle management services. She made these comments while speaking at the *Executive War College* in May. White explained that what private health insurers pay for laboratory tests has declined steadily for many years. That fact—plus the changes to Medicare lab test fees coming under PAMA—will require all labs to be more disciplined in how they manage their billing and collections.

"While the payment environment is already challenging, CMS is implementing PAMA, which, for labs, means there is a real need for financial discipline," advised White. "Now that CMS is doing its market-based exercise on pricing, we need to ask: Will the clinical lab industry actually get a market-based pricing system? And, will labs have the financial discipline required to do the reporting for market-based pricing accurately?

"Early this year, the industry acknowledged the challenges in collecting and reporting this information by requesting a delay, and CMS acknowledged those challenges by giving our industry a 60-day delay," she explained.

CMS plans to implement the PAMA market-based pricing on Jan. 1, 2018, and originally required labs to report private payer prices by March 31, 2017.

After labs had trouble using CMS' data reporting system, CMS delayed the reporting deadline until May 30, 2017. The date for CMS to implement market-based pricing is unchanged. *(See TDR, April 3, 2017.)*

Incomplete Data Submitted

"Part of the reason for that delay is because the number of labs that submitted data through March 30 was much lower than CMS anticipated, and the level of information labs delivered was also much less than CMS anticipated," White commented. "This tells us that, despite all the discussion about how medical labs are using big data and data analytics, our systems are not prepared to do the reporting needed for this complex data-collection and reporting exercise.

"For the clinical laboratory industry, this is not the first time we've encountered a market-based pricing scenario and it comes at a difficult time," she said. "There will be changes in FASB's rules for revenue recognition, and those changes may affect how labs capture, retain and analyze reimbursement data.

"Right after PAMA prices go into effect next year, publicly-held companies that operate clinical labs will be subject to a new set of accounting rules," White explained. "Then, in the following year, 2019, private companies will have to comply with rules that require even more stringent analysis of our revenue-recognition methodology.

"The rules will affect how we determine contractual allowance, the granularity to measure payer and payer-plan performance, as well as collectability for primary, secondary, and tertiary payers including patient responsibility," she said. "All of these changes will happen immediately after the PAMA lab price cuts go into effect at the beginning of 2018.

"Consider the problems labs have had in preparing for PAMA," White added. "Labs had so much trouble that they asked for an extension in the timeline for the PAMA process itself and this request came after laboratories had two years to pull the PAMA data together. Clearly, labs have had trouble analyzing and recording the data.

"Some of these issues with which labs are struggling have to do with the complexity of the reimbursement environment itself," she said. "But in an age when we have standard transactions and all payers must use a standard explanation of benefits and electronic remittance advices in their reporting and adjudication of claims, it's far easier to accumulate this data than it was in the past.

"Yet, outdated and inadequate financial systems in healthcare and the laboratory sector lack the capacity to precisely capture, retain, and account for every external data element and internal user action associated with full claims adjudication," she added. "At the same time, retroactive CMS guidance on data reporting requirements did not allow the industry time to adopt new systems and processes that facilitate accurate reporting. Without this level of accounting granularity and auditability, it has been impossible for many labs to produce accurate and complete PAMA reporting.

Is CMS Gaming The System?

"So, that's the environment in which labs are operating," she explained. "Now, as an industry, we need to address the question of whether CMS is gaming the system to ensure that there will be a cut to the Part B clinical laboratory fee schedule

"I say that because it appears that CMS excluded almost all of the hospital labs from contributing data," explained White. "Then, after acknowledging that hospital labs had to contribute some data, CMS limited the participation of hospital labs to only those that have an NPI [National Provider Identifier].

"In other words, did CMS use the NPI requirement to eliminate a large portion of the hospital market from reporting its private payer lab price data?" she asked.

Concerns About Hospitals

"If you look at the laboratory industry in general, you'll see that hospitals perform more than half of the laboratory tests done in the United States," White explained. "Half of the total number of tests are for inpatients and the other half is for outreach and outpatients. There are approximately 5,000 hospitals in the United States, and about 80% of them provide outreach services.

"Thus a large population of hospital facilities are part of the clinical lab market," she said. "Therefore, excluding this market is fairly detrimental to the process of collecting private payer lab test prices as described in the PAMA statute.

"Essentially, hospitals are more likely to affect a market-based payment program than independent labs, because many hospital contracts are negotiated as a percentage of a billed amount," White explained.

"Meanwhile, independent labs represent about 34% of all laboratories," she added. "The larger labs make up about 30% to 50% of the pie and the rest are smaller, esoteric, and specialty labs.

"If we were to look at test volume by facilities and *all labs participated*, hospital outreach would represent about 44% of the data, while the biggest lab companies would be about 28%, and the rest of the independent labs would make up about 28% of the test volume," she said.

"Data that XIFIN has collected over the years show that, when using a weighted average, private payer prices paid to the big labs are almost 45% below the current Medicare Part B clinical lab fee schedule," she said.

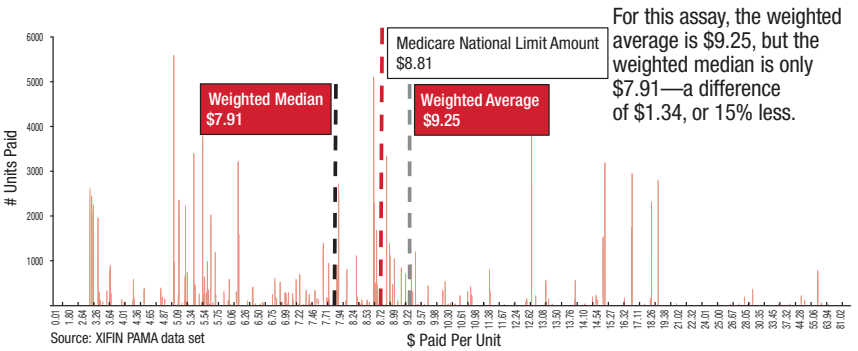
"By comparison, the weighted average of the prices private payers pay to the entire remainder of the clinical lab industry is about 8% greater than current Medicare Part B lab prices," White continued. "The prices private insurers pay to hospital laboratory outreach—meaning those with and without an NPI—is an even more dramatic difference. The weighted average of hospital lab outreach prices is about a 32% increase to the existing Medicare Part B clinical lab fee schedule.

'Weighted Median' Versus 'Weighted Average': Each Has Different Consequence in Price-setting

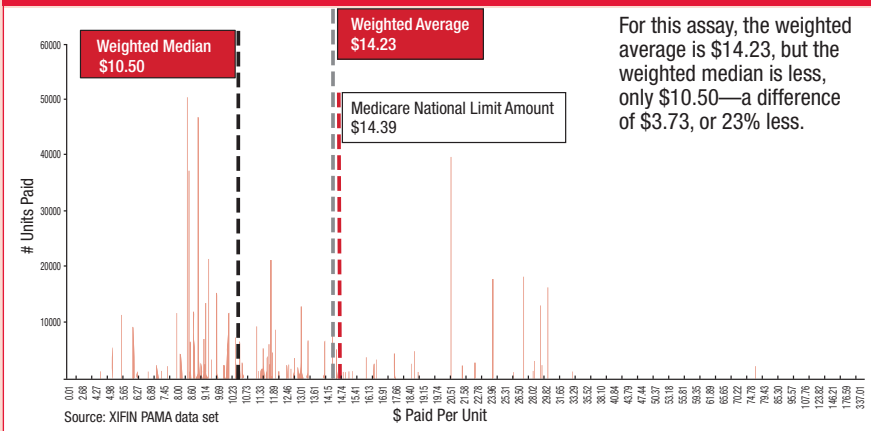
THERE ARE VALID CRITICISMS OF THE FINAL RULE that the federal Centers for Medicare and Medicaid Services published to implement the private payer market price reporting requirement of the Protecting Access to Medicare Act (PAMA).

One of those criticisms is that CMS is using a weighed median calculation to analyze the private payer market prices that labs reported earlier this year. In her presentation at this year's *Executive War College*, Lâle White, CEO of XIFIN, Inc., pointed out that the weighted median calculation is not suited for financial analysis. Rather, she noted, the weighted median is better suited for Quality Control and removing outliers. Using XIFIN's data from hundreds of millions of lab test claims her company handles each year for more than 200 labs, she showed the difference in weighted median versus weighted average for two different clinical laboratory tests.

Weighted Median vs. Weighted Average: CPT 85027 Complete CBC



Weighted Median vs. Weighted Average: CPT 80053: Comprehensive Metabolic Panel



"Therefore, what we would actually see if every clinical laboratory participated in submitting their private health insurer price data is about a 3.8% increase over the existing Medicare fee schedule," she noted.

"But, what if we don't get a full participation level among hospital labs in the CMS study," she asked. "We focus on these labs because they really move the needle.

"At 100% participation—and including the private payer price data from independent labs—we would get a 3.8% increase over the existing Medicare Part B clinical laboratory fee schedule," she explained. "At 75%, we see a decrease of 1.7%. At 50% the decrease rises to 7%, and at a 25% rate of participation among hospital labs, we see a decrease of 13%. If there's only 10% participation, Part B lab prices would decrease about 16% from current levels.

"These numbers show the importance of how private payer price reporting is done and which labs participate in the actual reporting of PAMA data," she explained. "This is why the **ACLA**, **NILA**, and other lab associations have told CMS that the dataset that's being provided is insufficient to provide a true market value of lab test prices. We need greater participation to achieve a true market-based price.

"For labs, this means the data capture of private payer prices is absolutely critical," she said. "Labs need to consolidate multiple payments when there are partial payments on a test and still be able to report an accurate allowable. When payers get multiple units of a single CPT code, the adjudication process is faulty, causing payers to report the wrong number of units coming back on the explanation of benefits. This has to be reconciled.

Allowables in Focus

"Also, labs need to identify claims that are still in process because only fully-paid claims are subject to reporting," stated White. "That means that appeals, redeterminations, and corrected claims all have to be taken into consideration. Labs must process the contractual allowance accurately and note that—when payers actually pay for claims and do recoupments and adjustments—they often do not recalculate the allowable.

"In addition, labs need to identify the primary payer even if submitting a claim with a primary and a secondary payer," she added. "Sometimes the payer comes back with a different primary payer, which alters the allowable. Labs have to be aware of that and know what the actual allowable is.

"To do this well and accurately, labs needed to review their data for a fairly significant period of time," said White. "When a lab doesn't review its private payer price data over time, it could easily report that data inaccurately. That could prove expensive, because the penalties associated with under-reporting, over-reporting, and not reporting can be $10,000 per day.

Lessons Learned

"For all of these reasons, there are lessons from this PAMA exercise," she said. "First, we learned that if the billed amount equals the allowable amount, your fee schedule is probably off, and your lab is under-billing. We've learned that when payers pay below the contracted fee schedule, we need to identify that and talk to the payer about correcting their reimbursement files.

"We also learned that we should not negotiate contracts that are a percentage of Medicare," continued White. "And, the retention of source documents, meaning the documents that support the electronic invoices labs submit and the remittances that are returned, are essential for audit purposes. Also, labs need to optimize electronic transactions because manual payment posting and processing is fraught with errors.

"One other lesson is that the audit process is one of the most critical elements in PAMA reporting," she advised. "Having the reporting structure in place that allows your lab to audit easily and be able to produce the documentation for audits will be critical because private Medicare auditors are incentivized to find errors." TDR

—By Joseph Burns

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Details Emerge About End of 31-Year Lab JV

Hospital, pathology group, Quest Diagnostics were partners in CompuNet lab joint venture

CEO SUMMARY: Quest Diagnostics is no longer an equity partner in the CompuNet Clinical Laboratory joint venture, which has operated successfully since its founding in 1986. Typical of other lab JVs and inpatient lab management agreements that the hospital or health system partners do not renew, none of the owners of CompuNet will comment on why the lab JV ended. Several sources offer informed perspectives on the reasons why this joint venture changed, but the truth is largely unknown.

IT IS ALWAYS SIGNIFICANT when a laboratory joint venture involving a commercial lab company, a hospital, and a pathology group survives for more than three decades—then comes to an unexpected end.

That is the case with **CompuNet Clinical Laboratories** of Dayton, Ohio. Last month, after 31 years as a lab joint venture, that partnership dissolved when **Premier Health** bought out the ownership stake that **Quest Diagnostics** held for many years. When the deal becomes effective in June 2018, it will leave Premier Health and the **Valley Pathology Group** as the two equity owners of CompuNet.

When new lab joint ventures are announced involving a hospital or health system and a commercial lab company, they typically get ample publicity. At the start of these ventures, the parties grant interviews and express optimism about the great synergy and results the partners expect.

But the opposite happens when a laboratory joint venture between a hospital and a commercial lab company terminates. These JVs or hospital lab inpatient management agreements often end quietly, typically without an announcement from any of the parties.

In the case of CompuNet, the health system partner issued a news release about its purchase of Quest's equity interest. This public statement contained useful hints about why it acted to end Quest's role in this lab joint venture. *(See TDR, June 26, 2017 and sidebar on page 17.)*

Declined To Be Interviewed

But, when approached for additional comment, each of the three equity owners declined to grant an interview with THE DARK REPORT. One reason to decline such an interview may have been the existence of tough non-disclosure clauses in the termination agreement. Such agreements are common in lab joint ventures and inpatient lab management contracts that involve a commercial lab company failing to renew its contract with a hospital or health system partner.

To get more insights into the events at CompuNet, THE DARK REPORT interviewed

several individuals knowledgeable about the lab JV's recent history and some unlikely issues that may have played a role in Premier's decision to end Quest's role in CompuNet by purchasing its equity share. Each source asked to remain anonymous.

History Of CompuNet JV

One source said, to have context for the recent events, it was important to understand the history of CompuNet and how the three owners were themselves acquired during the 31-year existence of the lab joint venture.

"In 1986, the three original members of the partnership were **International Clinical Laboratories** (ICL), the Valley Pathology Group, and the for-profit arm of **Miami Valley Hospital**," said the lab historian in an interview. "At that time, this for-profit venture was called **Med America Health System.** The partners stayed together even though the names of the parties changed. The entities remained the same.

"One name change among the CompuNet partners came in 1988 when **SmithKline BioScience Labs** purchased one of its biggest competitors, ICL. Later renamed **SmithKline Beecham Clinical Laboratories** (SBCL), it became one of the largest public lab companies in the United States.

Large Dayton Health System

"Next, in the 1990s, Med America became Premier Health, which today is one of the largest health systems in Dayton. After Med America transitioned to Premier, it formed an alliance with three other area hospitals: **Good Samaritan Hospital**, **Atrium Medical Center**, and **Upper Valley Medical Center**," the historian noted.

"At about the same time, **Kettering Hospital**, which was the other major health system serving the Dayton area, did the same thing," she added. "That resulted in the development of two powerhouse health systems in Dayton: the **Kettering Health Network** and Premier Health. A few smaller hospitals have remained independent, but not many.

"Over most of the 30 years of the CompuNet lab joint venture, 845-bed Miami Valley Hospital was the largest hospital in the area," she said. "It was like the mothership, and its size was a factor when Premier Health was formed because Premier Health eventually decided to use the **Epic** electronic health record system.

"You wouldn't think the choice of an EHR would be a major problem for the lab JV, but it was because, in recent years, Premier wanted to push Epic's Beaker LIS into all the laboratories that were part of the Miami Valley federation of hospitals," she explained. "I believe what aggravated the problem was the fact that Premier and its partner, Miami Valley Hospital, didn't fully appreciate the clinical value and financial asset they had in CompuNet. They were focused on unifying the data and clinical management under one IT infrastructure.

Lab Value Is Unrecognized

"With CompuNet, Premier and Miami Valley Hospital had a capable clinical laboratory that served the inpatient, outpatient, and outreach sectors in effective ways," stated a different source with knowledge of these events. "But recognizing that fact—the clinical value that labs can leverage—can be a challenge for some hospital administrators. They don't have a thorough understanding of the complexity of the lab business and may have nothing with which to compare it. Therefore, they don't recognize the full value of the lab as an asset.

"Thus, around 2015, when Premier began pushing the Epic Beaker LIS into the different lab locations and the hospital administrators didn't recognize the value of the CompuNet JV lab, those two factors started to break down the partnership," he said.

Why Would a 31-Year-Old Lab Joint Venture End? The Three CompuNet Partners Are Not Talking

MANY CLINICAL LAB PROFESSIONALS are interested in the lessons learned from each lab joint venture or inpatient lab management contract when a hospital or health system partner ends its JV with a commercial lab company partner—such as happened recently at CompuNet Clinical Laboratories.

Such interest is well founded. There are many hospitals and health systems where pathologists and lab managers are aware that their hospital administrators meet with commercial lab executives who pitch the benefits of selling the hospital's lab outreach business, creating lab joint ventures, or entering an agreement for a commercial lab to manage the hospital's inpatient laboratory.

In the case of Quest Diagnostics' exit from the CompuNet lab joint venture, the only public statement that any of the three partners made was a press release that Premier Health issued. Premier Health is the partner that had just purchased all of Quest's interest in CompuNet. It will own 85% and Valley Pathology Group will own the remaining 15%.

The news release contains language that suggests there were several key issues that the remaining two partners hoped to resolve by having the commercial lab partner exit this lab JV. In its analysis of these topics in its previous issue, THE DARK REPORT wrote, "Taken at face value, Premier Health was saying in the announcement that, without Quest as a partner, it would:

- "Gain 'local oversight of lab testing services... to meet patients' needs.'
- "Ensure more rapid turnaround times for patient lab results.
- "Achieve greater economies of scale.
- "Control the costs of lab services.
- "Have 100% local control to enhance testing capabilities which impact the local community."

All of these statements imply that Premier Health believed it was not realizing these benefits in the three-way lab joint venture.

None of the three partners will comment on this situation. Several individuals with knowledge of events at CompuNet have opinions and wish to remain anonymous. One source believes that service issues were not the deciding factor, stating that, "In my personal opinion, Quest was a good partner. The greater problem was Premier's desire to implement the Epic Beaker LIS in all lab facilities.

Battle of IT Departments

"In recent years. there was a constant battle involving the IT departments from Quest, Epic, and Premier IT on how to make the Epic Beaker LIS work," she continued. "The management team at CompuNet insisted that they needed to use Quest's secure lab system for the outreach business and billing. Currently, Beaker does not have comparable functionality that meets the needs of a competitive outreach laboratory business.

"I also think that administrators at Premier may not have fully grasped what an asset they had with CompuNet and its potential to become a core lab that could serve the entire Dayton area, possibly even including the labs that were part of the Kettering Health Network," she said. "That is a moot point now, in part because there were so many disagreements in the IT departments, and now Premier is the majority owner of CompuNet."

"Of course, many lab professionals will recognize that the Epic Beaker LIS has specific strengths, but it is not yet a complete and effective solution for labs that need full LIS functionality," observed the source. "That was the problem with forcing the Premier lab sites to run the Epic Beaker system."

Separately, and starting 18 years ago, another development happened that

would eventually play a role in this story. "In 1999, following Quest Diagnostics' acquisition of SBCL, it became the equity partner in CompuNet," noted the historian. "Just as SBCL had inherited the lab joint venture from ICL, Quest inherited the joint venture when it purchased SBCL.

"After Quest became part of the lab JV, it often deferred toward the two local owners of the lab," she explained. "That may have been, at least in part, because Quest had only a 33% share of the partnership.

"As a result of Quest's hands-off approach, the CompuNet partnership stayed together for many years," she said. "The original CompuNet joint-venture contract in 1986 was for seven years, but there was always an out clause on the initial and recurring renewal contracts that allowed any party to leave the partnership after giving a one-year notice.

"So it happened that, about three years ago, Premier wanted to renegotiate the agreement or get out of this laboratory joint venture," commented the second source. "It's not known exactly what Premier planned, but they may have made an agreement with the Valley Pathology Group to gain a larger ownership stake in CompuNet. At that time, it was believed that Premier wanted to increase its stake from 33% to 51%.

Contract Renegotiated

"Sometime in 2014, the contract was renegotiated," he added. "As a result of the negotiations, the physicians at Valley Pathologists agreed to sell about half of their 33% equity share to Premier. The pathologists retained a 15% ownership stake. Premier got 51% and Quest retained its 33%. That was the agreement in 2014.

"But Premier wanted to gain complete control of CompuNet management," he stated. "Despite the fact that Premier held a 51% stake, each partner still had an equal vote on the board. When Premier realized it couldn't gain complete control of CompuNet, and it couldn't force CompuNet to accept the Epic Beaker LIS because it may have had a negative effect on the outreach business, Premier called for a second renegotiation of the CompuNet business agreement.

"This second round of negotiations began in January 2016," he recalled. "The result was the press release in June announcing the changes in ownership for the lab joint venture. The final contract wasn't completed until just last month for reasons that are unknown.

"By this time next year, Premier will have an 85% stake in CompuNet and Valley Pathologists will have the remaining 15%," he added. "Quest will have no role in the ownership of CompuNet.

Quest Keeps Reference Tests

"While Quest will not have an ownership role in CompuNet for the first time in 32 years, it will still have a place in this market because it may continue to be the reference laboratory for CompuNet in about 10 counties in southwest Ohio," explained the first source. "In addition, Quest has a few long-term hospital contracts that have existed since before the joint venture was formed.

"In addition, Quest could now compete with CompuNet for the outreach business in this region," she explained.

"Of course, now that Quest has left the Premier Health system, technically it could make a deal with Kettering Health Network, which is something that has long been speculated," she offered. "Quest couldn't do that while it was under contract with Premier Health. Now, it's free to do so."

Whatever the truth about this situation, the statements in the Premier press release remain the most definitive official statements about motives to end this long-running lab joint venture. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's an update on **Theranos**, the troubled lab company that is struggling to stay alive. Once again, reporter John Carreyrou of *The Wall Street Journal* scooped his peers by reporting that Theranos has listed its corporate offices for lease. For lab companies shopping for office space in Palo Alto, Calif., Theranos has listed its 116,172 square foot building. Rates are negotiable, portions of the space can be leased, and terms through August 2029 are available. The company continues to fight several lawsuits by investors and other companies that had dealings with Theranos.

MORE DOCS GUILTY IN BIODIAGNOSTIC LAB FRAUD

Last month, five more doctors pled guilty to charges they accepted bribes from **Biodiagnostic Laboratory Services**, the defunct lab that was based in Parsippany, N.Y. This brings to 50 the number of convictions of physicians, executives, and others who accepted bribes and other forms of illegal kickbacks from BLS.

NEW LAB COMPANY TO SERVE DOCTORS WITH IN-OFFICE LABS

Having operated **In-Office Pathology Inc.** for more than a decade, its owners are expanding into new medical specialties. Bernie Ness and Joe Plandowski recently organized **In-Office Cytometry Inc.**, to help physicians in the fields of ENT, GI, infectious disease, rheumatology, and allergy to set up and operate in-office laboratories to perform flow cytometry testing.

TRANSITIONS

- Ran Whitehead joined **Pacific Diagnostics Laboratories** of Santa Barbara, Calif., as General Manager. Whitehead's executive experience includes **PeaceHealth Laboratories**, **SED Medical Laboratories**, **Lee Memorial Health System**, **Home Healthcare Laboratories of America**, **Baptist Hospital** (Nashville), **Moses Cone Health System**, **International Clinical Laboratories**, **Smith-Kline BioScience Labs**, **Duke University Medical Center**.
- In May, Richard L. Faherty left **Bio-Reference Laboratories, Inc.**, where he served as Executive Vice President, Administration. Faherty had been with BRLI since 1997.
- **NanoString Technologies** appointed Chad Brown as Senior Vice President of Sales and Marketing. He has held positions with **Qiagen**, **Roche Diagnostics**, **Rotech Healthcare**, **Apria Healthcare**, and **Chiron Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 7, 2017.