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EXTENDED YEAR-END ISSUE

Top 10 Lab Stories of 2017

Dominated by Part B Cuts

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

ACLA Sues HHS over Market Price Study, Fee Cuts

IT'S A LONG-AWAITED DEVELOPMENT! Today, a federal lawsuit was filed against the **Department of Health and Human Services** (HHS) by the **American Clinical Laboratory Association** (ACLA).

The lab association is asking a federal judge to review specific actions taken by the **Centers for Medicare and Medicaid Services** in how it is implementing sections of the Protecting Access to Medicare Act (PAMA).

In its press release, ACLA stated, "The government agency that runs the Medicare program failed to follow a congressional directive to implement a market-based laboratory payment system, thereby jeopardizing Medicare patients' access to vital laboratory services." The lawsuit was filed in the United States District Court for the District of Columbia.

ACLA further said, "The lawsuit asserts that CMS, operating under the purview of HHS, ignored congressional intent and instituted a highly flawed data reporting process in advance of setting market rates under the Protecting Access to Medicare Act (PAMA). Contrary to Congress's directives, the overwhelming majority of laboratories were prohibited from reporting private payer data. As a result, CMS failed to protect access to laboratory services for Medicare beneficiaries. This flawed process could cause serious financial harm to potentially thousands of hospital, independent and physician office laboratories, and make it harder for Medicare beneficiaries to get access to medical testing, particularly in remote rural areas and in nursing homes that depend on laboratory testing services."

One interesting twist in this litigation is that ACLA is represented by an attorney who was formerly the Deputy Associate General Counsel for Litigation, CMS division of HHS. Mark D. Polston, a partner at **King & Spalding**, is lead counsel for ACLA.

One the four things for which ACLA seeks a judge's ruling is this request: that the court issue an "injunction that (1) directs the Secretary to withdraw or suspend his final rule until such time as it can be brought into compliance with the statute, and (2) directs the Secretary to withhold applying the new Clinical Laboratory Fee Schedule until such time as the Secretary has made appropriate revisions to his final rule." TDR

Top 10 Lab Stories of 2017 Dominated by Part B Cuts

Events in 2017 will trigger major disruptions in both clinical lab and anatomic pathology sectors

CEO SUMMARY: In hindsight, 2017 is likely to be remembered as a milestone year that launched several disruptive developments that will reshape the lab industry moving forward. For the clinical laboratory sector this year, CMS confirmed its intent to slash Part B clinical laboratory test prices aggressively, effective Jan. 1. For the anatomic pathology sector this year, the FDA cleared the first digital pathology system and whole slide imaging for use in the primary diagnosis of most types of tissue.

HISTORY WILL PROBABLY RECORD 2017 as the year that sparked fundamental and far-reaching changes to clinical laboratories and anatomic pathology groups.

Viewed strategically, the 12 months ending in 20 days was unlike any in the past three decades for laboratory medicine. Actions taken this year likely will exert major influence on how medical laboratories of any type or size operate, provide lab testing services, and earn remuneration from payers and patients for many years into the future.

This is one conclusion to be drawn from a review of THE DARK REPORT'S list of the Top 10 Lab Industry Stories for 2017. Further, the year's developments in several specific areas of healthcare and laboratory medicine represent pivot points. In each case, whatever was the norm pre-2017 will be different post-2017.

Here are three examples of pivot points that are likely to create a different post-2017 environment for labs compared with the pre-2017 period:

- Release of the final Medicare Part B clinical laboratory test fee cuts in November.
- FDA clearance of the first digital pathology system and whole slide imaging for use in primary diagnosis in April.
- Implementation of genetic test prior-authorization programs by two payers covering 80 million beneficiaries that happened in July and November.

Moving into 2018, every clinical laboratory and anatomic pathology group will need to revise their strategies to respond

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to the most significant developments of 2017. Lab managers will need to design these strategies to help their labs adapt to healthcare's transition from silos of reactive care to integrated delivery networks that focus on keeping patients healthy. Doing so will include helping physicians use lab tests to diagnose patients with chronic conditions earlier and collaborating with physicians to manage those patients to keep them out of hospitals.

Payers Become Stingier

Events of this year, as reflected in the list of the Top 10 Lab Industry Stories for 2017, provide evidence that payers—both government and private—grow stingier with reimbursement, are more willing to exclude labs from their networks, and are determined to conduct more frequent and rigorous audits of lab test claims.

Medicare officials and executives at health insurers have some justification for their actions. The increase in fraud involving lab testing is a top 10 lab story in 2017. Moreover, in the face of this increased fraud, the failure of federal and state prosecutors and regulators to take decisive action against the most obvious law-breakers leaves payers with few options other than to enact Draconian coverage requirements.

Use in Strategic Planning

Each year, many clinical labs and pathology groups use THE DARK REPORT's list of the Top 10 Lab Stories as the basis for strategic planning sessions with their pathologists and senior management. It is recommended that these labs include some additional developments in these planning sessions.

For example, what are the implications of the FDA's clearance of the CLIA-waived CBC test developed by **Sysmex?** *(See TDR, Nov. 20, 2017.)* This approval came last month and sales of the instrument system and CBC test won't start until 2018. Sysmex told THE DARK REPORT that it developed this CLIA-waived CBC test because it believes that more lab testing will disperse outside the central laboratory to near-patient and point-of-care settings.

Sysmex also believes that integrated delivery networks, paid a capitated rate or a budgeted payment, will want more lab tests to be performed in near-patient settings. This would allow physicians to diagnose patients on the same office visit, then send them on their way with an electronic prescription waiting for them at the nearest pharmacy. These methods provide better and more timely patient care by making doctors' offices more productive and lowering the cost of care.

Model for Dispersed Testing

Naturally, we are still several years from widespread adoption of this diagnostic testing model. But this new FDA-cleared, CLIA-waived CBC demonstrates that at least one *in vitro* diagnostics (IVD) manufacturer is ready to upend long-standing paradigms in clinical laboratory operations. In this way, a model of lab testing that is more distributed or dispersed is developing throughout the integrated delivery systems and ACOs that will dominate healthcare in coming years.

One of the more interesting stories on this year's list is the observation that the paths of hospital and health system laboratories are now diverging from the paths of independent lab companies. THE DARK REPORT is first to identify and describe this development. *(See TDR, Nov. 20, 2017.)*

Divergent Paths

If this trend continues, it could represent the pendulum swinging back in favor of hospital laboratories after more than a decade of dominance by the nation's largest lab companies. And, it could be one reason why many lab professionals would consider that there was some good news for hospital labs in 2017 after all. **TDR**

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TDR 2017 TOP LAB STORY 1

CMS Sticks by Decision to Deeply Cut Medicare Part B Lab Test Fees

SHORT OF A MIRACLE, the clinical laboratory industry is less than three weeks from the single most financially-disruptive event of the past 30 years. On Jan. 1, the federal **Centers for Medicare and Medicaid Services** will impose deep cuts to Part B clinical laboratory test fees.

CMS officials say these fee cuts will produce savings of $670 million in 2018 and will be followed by additional fee cuts in the following years 2019 through 2022. *(See TDRs, Oct. 9, Oct. 30, and Nov. 20.)*

Across the nation, labs of all sizes are bracing for the coming financial storm. It is widely recognized that the most vulnerable will be community lab companies, particularly those serving nursing homes almost exclusively and those laboratories that are in small and rural hospitals. These labs face bankruptcy, sale, or outright closure.

But even the nation's largest lab companies face significant vulnerability. For the past two decades, they have given health insurers deeply-discounted lab test prices in exchange for exclusive or near-exclusive provider status. While taking less from commercial payers, these labs subsidized operations with fee-for-service payments from Medicare.

For this reason, observers believe that, once Medicare fee cuts bite into their revenue, the billion-dollar lab companies will need to go back to the big health insurers to win higher prices through renegotiations. But it's not likely that tight-fisted health insurers will be receptive to such overtures.

TDR 2017 TOP LAB STORY 2

Lab Companies Decide to Sell, Exit Because of Medicare Test Price Cuts

IT'S OBVIOUS TO EVERYONE who understands the clinical lab marketplace that the severe lab test price cuts soon to be imposed by Medicare officials will financially devastate most sectors of the clinical laboratory industry.

In fact, even in early 2017—almost a year in advance of implementation of these fee cuts—owners of clinical laboratories took steps to exit the business and sell or shut down their labs.

That was certainly the case when **Peace Health** of Eugene, Ore., offered for sale last winter its **Peace Health Laboratories**. At the time, **Quest Diagnostics** eagerly snapped up the assets and began closing some of PHL's lab facilities and patient service centers in many smaller communities in Oregon and Washington, according to what PHL's CEO told THE DARK REPORT. *(See TDR, Feb. 21, 2017.)*

Another example happened last month, when **Vista Clinical Diagnostics** of Clermont, Fla., sold the part of its business that serves office-based physicians, while keeping its nursing home business. **Laboratory Corporation of America** was the buyer. *(See TDR, Nov. 20, 2017.)*

In discussing his owner's decision to sell, PHL CEO Ran Whitehead stated, "our best projections indicated that we would experience about a 20% reduction in revenue just in the first two to three years of the PAMA Medicare fee cuts... There is no way smaller labs and hospital lab outreach programs have a profit margin sufficient to absorb a 20% reduction in lab test fees."

TDR 2017 TOP LAB STORY 3

FDA Clears Digital Pathology For Use in Primary Diagnosis

FOLLOWING YEARS OF DEVELOPMENT, the still-nascent field of digital pathology and whole slide imaging gained a significant victory. On April 12, the **Food and Drug Administration** cleared the first digital pathology system and whole slide imaging for use in the primary diagnosis of most types of tissue.

The honor of first regulatory clearance went to **Philips** and its Philips IntelliSite Pathology Solution (PIPS). Experts believe that other vendors of digital pathology systems now have a road map to follow to obtain FDA clearance for their digital pathology products. *(See TDR, Apr. 24, 2017.)*

There is still much uncertainty as to how quickly other DP systems can gain regulatory clearance and whether a critical mass of anatomic pathology laboratories throughout the United States will rapidly accept DP systems.

What is clear is that digital pathology and whole slide imaging is disruptive to a medical specialty that still relies on the same light microscope technology that Rudolf Virchow and other pathology pioneers used in the 19th century.

Further, at a time when the world is going digital, the power of whole slide images is in how it gives pathologists the capability to move cases in real-time from the histology lab that processed the tissue to a subspecialist pathologist located anywhere in the world.

Now that the FDA has signaled its readiness to clear one product for market, it would be timely for every anatomic pathology lab to develop strategies for when and how they will use DP systems.

TDR 2017 TOP LAB STORY 4

Prior Authorization of Genetic Tests Goes Mainstream During 2017

THIS DEVELOPMENT MAY NOT BE EQUALLY AS DISRUPTIVE as others on the list of the lab industry's Top 10 lab stories of 2017. Major health insurers' actions to impose prior-authorization requirements for genetic tests have introduced significant challenges to any lab company or hospital lab performing molecular and genetic testing.

Since the summer, **Anthem** and **UnitedHealthcare** instituted prior-authorization requirements for genetic tests. Anthem's program took effect July 1, and UnitedHealthcare's started on Nov. 1. Collectively, the two insurers have 80 million beneficiaries, so these actions affect many—if not all—of the nation's lab companies.

In the weeks following the launch of these prior-authorization programs, numerous lab companies reported serious problems when working with their client physicians and the payers to obtain timely preapproval. One consequence of these developments is that many labs performed genetic tests to support patient care while knowing that they would not be paid for these claims. *(See TDRs, June 26, Aug. 7, and Aug. 28.)*

More prior-authorization should be expected from such companies as **Avalon Healthcare Solutions**, LabCorp's **BeaconLBS**, and **InformedDNA** that already have contracts with health insurers to manage lab test utilization.

TDR 2017 TOP LAB STORY 5

Lab Test Fraud Is Growing Problem, Scammers Now Recruiting Hospitals

A NEW WAVE OF LAB TEST FRAUD is costing Medicare and private health insurers multiple billions of dollars annually.

Federal and state prosecutors are failing to stay up with the flood of fraudulent operators who use over-priced, medically-unnecessary clinical laboratory tests to suck billions of dollars out of the U.S. healthcare system.

This fall, THE DARK REPORT published the lab industry's first description of an arrangement often called HOPD, for Hospital Outpatient Department. This strategy is a new variant on the long-established "pass-through billing" scheme. *(See TDR, Oct. 30, 2017.)*

Simply described, the fraudulent operator will persuade a hospital to enter an agreement whereby the operator will generate lab specimens from the outreach market; as an in-network provider, the hospital will bill for all these lab tests and then will split the proceeds collected from health insurers with the operator. Typically, most or all lab tests involved in this arrangement are performed by the operator's lab companies and not within the hospital lab.

In 2017, at least three health insurers filed lawsuits against all parties involved in an HOPD arrangement. Defendants in these cases will include the organizers of the scheme, the hospital that submitted the bills, and the independent lab companies that performed the tests.

UnitedHealthcare, **Blue Cross Blue Shield of Mississippi**, and **Aetna** filed these lawsuits during 2017. Pathologists and managers at hospital labs need to be aware of these developments.

TDR 2017 TOP LAB STORY 6

Clinical Lab 2.0 Is Way for Labs to Add Value with Lab Tests

IF THERE IS A GOOD NEWS STORY on this year's list of Top 10 Lab Industry Stories, then Clinical Lab 2.0 is it. This is a clinical and operational model for how laboratories can deliver added value that payers recognize and reward with value-based reimbursement.

Clinical Lab 1.0 is the classic transactional model of lab services that has served fee-for-service healthcare for decades. In this model, labs strive to increase the volume of specimens tested. The resulting lower average-costs-per-test expand the profit margins from fee-for-service payments. But how do lab 1.0 labs get paid when health insurers replace fee-for-service payments with value-based payment?

That's where clinical lab 2.0 becomes important. As the new, integrative model for lab testing services, lab 2.0 is designed to serve the needs of integrated healthcare systems. It supports the delivery of precision medicine and helps physicians gain more value from lab testing services. As a result of such benefits, the clinical lab 2.0 organization earns reimbursement based on that added value. *(See TDRs, Jan. 30, May 15, and June 5, 2017.)*

Clinical Lab 2.0 was developed by the lab leaders participating in **Project Santa Fe**. They conducted a public workshop in Albuquerque, N.M., last month to teach this lab model and they plan more such educational events.

TDR 2017 TOP LAB STORY 7

Paths of Hospital Labs Diverge from Paths of Independent Labs

THERE IS NOW STRONG EVIDENCE that the paths of hospital and health system labs are diverging from the paths of independent lab companies. It is too early, however, to understand how this change will affect the status quo in the clinical laboratory marketplace. *(See TDR, Nov. 20, 2017.)*

For decades, hospital labs and independent labs tended to be organized and operated in a similar fashion. Whether it was a hospital lab or a commercial lab company, the instrumentation, workflow, and test menus had much in common. The major operational differences involved the need for hospital labs to serve inpatients.

That service model was a response to the reactive, siloed, fee-for-service-based healthcare system of the past 70 years. What is changing—and what now puts hospital labs on a different path—is the growth of integrated delivery networks and ACOs. It is generally accepted today that value-based reimbursement will dominate, that clinical care must be integrated, and that precision medicine will be the way to improve patient outcomes while reducing healthcare costs.

These developments put hospital labs at ground zero for all the clinical care activities within the communities they serve. These integrated delivery networks provide inpatient, outpatient, and outreach care. They find it valuable, if not essential, to have a full, longitudinal record of a patient's lab test data that has the same test methodologies and reference ranges.

TDR 2017 TOP LAB STORY 8

Payers Get Tougher with Lab Audits, Some Lab Firms Put into Bankruptcy

TOUGHER PAYER AUDITS are the talk of the lab industry these days. Some audits are aggressive enough to push the audited lab companies into bankruptcy.

The Medicare program has initiated several different types of audits. Most are conducted by private contractors who often can be awarded a portion of the funds recovered from the lab or other provider as a consequence of these audits.

Private health insurers also have increased the number of audits they conduct and the rigor and detail of those audits. Payers are asking labs to provide full documentation to show medical necessity for test claims. Documentation as to how they bill patients and collect the amount owed from patients is another subject of these audits.

One example is **Pharmacogenetics Diagnostic Laboratory** (PGxL), of Louisville, Ky., which was hit by a $26 million recoupment demand after a federal Zone Program Integrity Contractor (ZPIC) audit. PGxL filed bankruptcy because the amount of the recoupment demand equalled about three years of the lab's annual revenue.

A second pharmacogenomics lab company told THE DARK REPORT that a Zone Integrity Program Contractor conducted an audit in circumstances similar to those of PGxL. The recoupment demand totaled tens of millions of dollars. *(See TDRs, Jan. 9 and Jan. 30.)*

Labs can expect more frequent and more rigorous government and private payer audits.

TDR 2017 TOP LAB STORY 9

FDA Sidetracks Its LDT Regulation as New Administration Takes Office

RECOGNIZING THAT WASHINGTON, D.C., had a new administration and a different Congress, earlier this year, the **Food and Drug Administration** decided to set aside its declared plan to regulate laboratory-developed tests (LDTs).

On Jan. 13, FDA officials issued a discussion paper stating that the federal agency would defer its plans "to issue final guidance on the oversight of laboratory developed tests."

After this paper was issued, members of Congress released a draft bill that addresses LDTs. The bill was sponsored by representatives Larry Bucshon (R-Ind.) and Diana DeGette (D-Colo.) and is titled, the "Diagnostic Accuracy and Innovation Act."

Many in the clinical laboratory industry welcomed these developments. Since the FDA launched itself down this path in 2012, many laboratory professionals voiced valid objections to FDA regulation of LDTs.

In response to draft LDT guidance that the FDA issued in 2015, some in the clinical lab industry organized a response known as the Diagnostic Test Working Group.

A variety of players have common interest in preventing regulation of LDTs. Included in this group are labs with proprietary LDTs, investors in lab companies, the large national labs, and academic centers. For this reason, the last chapter in this story has yet to be written.

TDR 2017 TOP LAB STORY 10

Japanese Companies Invest, Divest in Two American Lab Companies

DURING 2017, TWO DIFFERENT JAPANESE COMPANIES made noteworthy and expensive deals involving lab testing companies. One deal was an acquisition worth as much as $1 billion to the seller. In the other deal, the seller lost $670 million.

The first transaction was the sale of **Miraca Life Sciences** by its owner, **Miraca Holdings** of Tokyo, to **Avista Capital Partners**. When the deal was announced on Sept. 22, the sale price was $176 million. But, only weeks later, the buyer and seller agreed to a further discount. When the deal closed on Nov. 20, the purchase price had been reduced to just $54.9 million. That is a 92% loss of value in just six years. *(See TDR, Nov. 20, 2017.)*

The second transaction was the acquisition of **Ambry Genetics** by **Konica Minolta**. The purchase price was $800 million with another possible $200 million to be earned, based on performance. Ambry's annual revenue was not disclosed. *(See TDR, July 17, 2017.)*

It is unusual to have two Japanese companies come to the United States and pay strong prices to acquire two specialty laboratory testing companies. From one perspective, these deals show that investors outside the United States believe there is the opportunity to purchase lab testing companies in this country.

From another perspective, the ability of these investors to harvest actual profits can be questioned. In the case of Miraca Life Sciences, that investment was a loss to the buyer. The outcome from the Ambry acquisition has yet to be determined.

Value of Miraca Falls By 92% from 2011 to 2017

➤Variety of market forces push down lab's value; is the same true at other independent lab firms?

➤➤CEO SUMMARY: Miraca Life Sciences amended its merger agreement with Avista Capital Partners after the lab lost value in the two months since the agreement was signed in September. Factors precipitating the revision were a significant decline in reimbursement rates, stiff competition from physician-office labs (POLs), and a loss of specimen volume to POLs and hospital labs, Miraca said. Also, MLS experienced what it called "lower profitability due to a change in product mix" and a limit to the number of tests that payers cover.

One buyer of an independent lab drove down the price it would pay to acquire the clinical laboratory company even further than it offered in September.

The sale of **Miraca Life Sciences** to **Avista Capital Partners** was announced in September 22. The press release issued that day stated that Avista would pay $175.6 million to purchase Miraca Life Sciences, the anatomic pathology company in Irving, Texas.

At the time, financial analysts were shocked that MLS' value had dropped sharply from the $725 million that **Miraca Holdings** paid for the lab company (then known as **Caris Life Sciences**) in 2011. The current purchase price represented a loss of value of 75.8%—or $548 million. *(See TDR, Nov. 20, 2017.)*

Since September, the sellers have dropped the price even more. On Nov. 20, Miraca revised the sale price down to just $54.9 million. That is a 92% loss of value (about $670 million) in just six years.

In an amendment to its merger agreement with Avista, MLS explained the multiple factors that caused the loss in value from 2011 through 2015. Among those factors were:

- A significant decline in reimbursement rates;
- Stiff competition from physician-office labs (POLs); and,
- A loss of specimen volume to POLs and hospital labs.

Also, MLS experienced what it called "lower profitability due to a change in product mix," and a limit to the number of tests that payers cover. Despite these problems, operations would continue without disruption, Miraca said.

➤Competition from POLs

For context on these issues, THE DARK REPORT interviewed Joe Plandowski, a co-founder of **In-Office Pathology**, a consulting firm in Lake Forest, Ill., that specializes in helping physicians develop in-house clinical and pathology laboratories. "If you look at what MLS says about changes in its business environment, competition from POLs was a significant factor," stated Plandowski. "There's no doubt

Miraca Life Sciences Explains Market Forces That Caused Further Drop in Lab's Sales Price

WHEN IT PURCHASED CARIS DIAGNOSTICS in November 2011, Miraca Holdings expected the acquisition would be the first step in its move to capitalize on the globalization of clinical lab testing. Miraca was betting that this factor would bring strong market growth. Instead, adverse market forces intervened.

To counteract those market forces, Miraca acquired **PLUS Diagnostics** in October 2013 from **Water Street Healthcare Partners**. At the time, PLUS was a cytology, histology, and molecular pathology lab that specialized in the same fields where MLS is strong: dermatopathology, hematopathology, gastrointestinal pathology, and genitourinary pathology. By adding PLUS Diagnostics labs in New Jersey and California, MLS became the nation's largest independent anatomic pathology lab company, it said.

Other steps to counteract adverse market forces were a consolidation and optimization of MLS' lab operations and an alliance with an information technology vendor. These steps were inadequate to the task, so that by last year, MLS reported that it had not fostered further growth and new investment was needed.

By September, MLS reached an agreement with Avista Capital Partners, a private equity company that specializes in healthcare. More bad news followed. In October, MLS said reimbursement declined and in November, it said an unnamed insurance company cut what it pays Miraca.

When it announced the new sale price on Nov. 20, MLS explained that, after the Avista deal was made public, "a significant decline of reimbursement from a major U.S. insurance company was recognized in early November. After a thorough investigation, it was identified that the insurance company had unilaterally cut reimbursement rates on certain pathology tests. The impact to MLS' profitability was assessed and countermeasures were discussed with Avista; however, given the significant impact to MLS' profitability, the merger agreement and basic enterprise value was amended.

Value Falls To $54.9 Million

"Based on the amendment, the basic enterprise value was revised to approximately $54.9 million (originally $175.6 million)," MLS said.

The result of these two factors was to change what had been an operating profit into a deficit, MLS. These new problems led to an amendment of the conditions in the sale to Avista and a downward "revision of basic enterprise value of $54.9 million," the company reported in an explanation to shareholders. The new sale price became final Nov. 20.

In explaining the change to shareholders, MLS reported that it had revised its profit and loss forecast from $10.7 million (or 16.5 billion yen) on Sept. 22 to $5.2 million (or 8.0 billion yen) on Nov. 20. When the calculations were reported, MLS said it used an exchange rate of $1 for 111.35 yen. MLS also was forced to recalculate its initial profit forecast of $6.5 million (10 billion yen) to $5.2 million (8.0 billion yen).

MLS serves more than 5,500 patients each day with diagnostic services in breast health, dermatology, gastroenterology, hematology and urology, the company said. After Avista acquires Miraca Life Sciences, it will be given a new name.

POLs took business from Miraca even though that was not the intent.

"In our business, it is typically larger physician groups that want to establish or expand in-office labs," Plandowski added. "If those physician groups are gastroenterologists, dermatopathologists, or urologists, then they often refer their specimens

to Miraca. That's why MLS lost those referrals to physician office labs (POLs).

"But also, Miraca, in recent years, lost volume to hospital labs because hospitals acquired physician office practices," he said. "Then, whatever work those doctors were sending to Miraca goes to the hospitals that own those practices.

Medicare Price Cuts

"When Miraca says product mix is a problem, that likely refers to urology testing for prostate biopsies," Plandowski speculated. "The standard for a prostate biopsy is 12 cores, and each one gets billed under code 88305. In 2018, the Medicare fee will be $70.20 for each core. Assuming a non-Medicare payer reimburses at $70.20, the total will be $842.40 for 12 cores.

"The problem is that Medicare will be using a G code (G0416) for prostate biopsies," he added. "That's a bundled code, meaning it doesn't matter how many cores a lab processes. Starting in January, Medicare will pay only $434.32 for that one bundled code, and that's the national average global fee that Medicare will pay, meaning it's not adjusted for geography.

"That bundled rate of $434.32 is only slightly more than half of what Medicare previously paid," continued Plandowski. "When a service or product has such a steep rate cut, that's called 'product mix deterioration.'

"If I were running a lab paid just half of what they got previously for prostate biopsies, I wouldn't do that work," he commented. "I would send all of those prostate biopsies to **Quest Diagnostics** and **Laboratory Corporation of America** because smaller labs will struggle to make money on that work. Smaller labs would be better off letting the big labs do it.

"Some people will say that labs need to adjust to the marketplace by using Lean methods and strong leadership," he added. "I would disagree because labs just can't make money if Medicare cuts payment by 10% next year, and 10% in each of the next two years after that, and then by 15% in each of the following three years.

"If Medicare does that, then the typical reimbursement will be too low to continue operations," he said. "Surely private third party payers will follow Medicare downward in reimbursement fees.

"Let's say the typical payment from Medicare is $152.67 and you take away 10% in each of three straight years," Plandowski explained. "That would be $137.40, then $123.66, then $111.30. Then, if the payment gets cut by 15% and then 15% percent again, then the average payment would be $94.60 and finally $80.41. That's a reduction of almost 50%. Labs cannot absorb that kind of loss. They will have no choice but to close, particularly if they have significant amounts of Medicare work.

Unable To Cover Lab Costs

"When a lab loses half its revenue, it cannot cover costs," he observed. "The only potential good news in all this is that the cuts of 10% in the next three years and then 15% in the following three years are the maximum by which Medicare officials can cut Part B lab test prices. There is no guarantee that Medicare will cut that deep, but they could."

Another issue that Miraca raised involves a sharp drop in insurance payment in October, and then an insurance company cut reimbursement further in November.

"That insurance company could be **UnitedHealthcare** or **Anthem**, meaning one of the two biggest health insurers," he said. "That's a guess. I am not aware of any recent deep price cuts from insurers or why an insurance company would target only Miraca with that type of lab test-price cut." TDR

—Joseph Burns

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Aetna Sues Hospitals over Alleged Lab-Billing Scheme

25-bed Oklahoma hospital in town of 1,336 submits 10,000 lab claims for $21M in 16 months

CEO SUMMARY: In September, Aetna filed a lawsuit in Pennsylvania accusing 14 defendants—including a hospital, a hospital management company, eight lab companies or lab management companies, two physicians, and two individuals—of defrauding Aetna, its client employers, and its members. The lawsuit is an example of a lab test arrangement in which independent lab companies and organizers use a hospital as an in-network provider to bill for clinical laboratory tests not performed by the hospital, the lawsuit alleged.

COMMERCIAL HEALTH INSURERS are taking legal action to stop a source of fraud that could be spreading to many areas nationwide. In the latest action, health insurer **Aetna** alleged in a lawsuit that a hospital in Oklahoma was used as an in-network provider to fraudulently bill for lab tests done off-site for patients who were not part of Aetna's network in Oklahoma but were from all over the country.

The lawsuit Aetna filed in U.S. District Court for the Eastern District of Pennsylvania on Sept. 29 alleged that the hospital and 13 other defendants defrauded Aetna, its members, and client employers of $21 million by submitting claims for clinical laboratory testing. The defendants include a hospital in Shattuck, Okla.; a hospital management company; eight clinical laboratories or lab management companies; two physicians, and two individuals.

The lawsuit describes a billing strategy that is similar to what is called a hospital outpatient department or diagnostics (HOPD) arrangement. In such arrangements, organizers persuade hospital administrators to allow the hospital to bill health insurers as an in-network provider for lab tests when the tests are not done in the hospital lab. Rather, the tests are done by other labs. In this case, the lab defendants did the testing and used the Oklahoma hospital lab to send fraudulent bills to Aetna, the lawsuit alleged.

Variants Of An HOPD

In some versions of the HOPD arrangement, a hospital will accession all specimens and refer them to the participating lab companies. In other versions, the labs accession the specimens and do the testing themselves, and the hospital lab submits claims for the tests that other labs perform. THE DARK REPORT described these practices in its Oct. 30 issue.

The use of this HOPD lab billing arrangement is an important story for pathologists and lab administrators serving hospitals and health system labs because hospital CEOs—particularly those in cash-strapped community and rural hospitals—may ask lab managers about these billing practices if approached with proposals to establish such arrangements.

To be clear, in its lawsuit, Aetna did not use the term "hospital outpatient department or diagnostics" or use the expression "HOPD arrangement." But what Aetna described is a variation on the pass-through billing strategy that participants use to submit claims for clinical services that often are billed at inflated prices.

One element of HOPD and other pass-through billing arrangements is that office-based physicians have a significant role in referring specimens to lab management companies. In such arrangements, physicians allegedly get illegal inducements or kickbacks from the defendant lab companies and may order substantial numbers of medically-unnecessary lab tests.

The Aetna lawsuit does not say that physicians ordered medically unnecessary tests. Of physicians, the lawsuit said, "Specifically, the lab defendants entered into arrangements with physicians (some of whom have contracts with Aetna) whereby the physicians were induced to refer Aetna members' specimens to the lab defendants."

Suit Named 14 Defendants

In court papers, Aetna named the 14 defendants as:

- **People's Choice Hospital, LLC**;
- **PCH Management Newman, LLC**;
- **PCH Lab Services, LLC**;
- **PCH Labs, Inc.**;
- **Mission Toxicology, LLC**;
- **Mission Toxicology II, LLC**;
- **Mission Toxicology Management Co., LLC**;
- **Sun Clinical Laboratory, LLC**;
- **Sun Ancillary Management, LLC**;
- **Integrity Ancillary Management, LLC**;
- **Seth Guterman, MD**;
- **David Wanger**;
- **Michael L. Murphy, MD**; and,
- **Jesse Saucedo, Jr.**

The hospital at the center of this arrangement is **Newman Memorial Hospital**, a 25-bed critical access hospital in Shattuck, a town of 1,336 residents. Court documents showed that last year, the defendants gained control of Newman, an in-network provider for Aetna, and changed its name to People's Choice Hospital.

Newman Also Has Lawsuit

Aetna's lawsuit explained that Newman Hospital has filed suit against many of the defendants. It seeks to terminate the relationship and recover damages including the money these defendants funneled through Newman. "As Newman explained in its pleading, the PCH defendants acquired 'nearly unfettered management and administrative control' over Newman..." the lawsuit said. After gaining control, the defendants caused Newman to violate its contracts with commercial insurers, purchased laboratory equipment, and hired a few employees for a 'lab' at Newman that was not actually used, the lawsuit alleged.

According to the lawsuit, Newman Hospital was struggling financially and the defendants gained control of the facility by promising to revamp the hospital and by convincing hospital administrators to sign a management agreement with People's Choice Hospital and PCH Management. After the arrangement took effect, the hospital submitted more than 10,000 lab test claims to Aetna over 16 months, the lawsuit said.

"Upon gaining control of Newman, People's Choice and PCH Management caused Newman to enter into agreements with the lab defendants, PCH Lab #1 and PCH Lab #2, who conspired with People's Choice, PCH Management, and the individual defendants to defraud Aetna and employers and employees whose health plans Aetna administers," the lawsuit said.

Doing so opened the door for lab test referrals from office-based physicians to flow into this HOPD arrangement. "The lab defendants paid and induced physicians all over the country to send urine and blood specimens to the lab defendants," court

Lawsuit Explains Alleged Lab-Test Scheme That Used Hospital to Defraud Health Insurer

IN COURT DOCUMENTS, ATTORNEYS for health insurer Aetna described the defendants' alleged fraudulent billing scheme involving a rural hospital and multiple lab companies.

"A physician informed Aetna Member No. 1 that the urine sample the physician collected from Aetna Member No. 1 in Jacksonville, Fla., would be sent to San Antonio, Texas, for testing and processing by Sun Clinical Laboratory, LLC," the lawsuit explained. "While Aetna Member No. 1's sample was sent to and tested by Sun Clinical Laboratory, LLC, defendants submitted a claim form to Aetna for Aetna Member No. 1 misrepresenting that Aetna Member No. 1's specimen was tested by and at Newman [Hospital in Oklahoma]."

In the court documents, Aetna included an image of a bill—commonly known as a "UB-04" claim form—that defendants submitted to Aetna for lab testing done for Aetna Member No. 1. The bill identifies Newman Hospital as the provider of lab services when in fact, those services were provided by Sun Clinical Laboratory, LLC, the lawsuit said.

"As a result of defendants' fraudulent claim, Aetna paid Newman $2,250, which was split up and distributed among various defendants. By comparison, if a large legitimate lab company with a national presence submitted a claim to Aetna for the same services defendants billed Aetna for Aetna Member No. 1, the legitimate lab company would have received and accepted approximately $120," the lawsuit said.

papers showed. "Defendants had these physicians inform the patients that their specimens would be sent to, tested, and processed by the lab defendants."

Misrepresentation Alleged

In the lawsuit, Aetna described the pass-through elements of the HOPD lab billing scheme. "Nevertheless, after the specimens were sent to and tested by the lab defendants, defendants misrepresented to Aetna that the specimens were tested by and at Newman [Hospital], thus causing Aetna, and employers whose health plans Aetna administers, to pay millions of dollars to Newman, which PCH controlled," the lawsuit showed.

"Defendants billed the laboratory claims as if they were completed at Newman because Newman has a contract with Aetna that contains high reimbursement rates for lab services performed by and at Newman," said the lawsuit.

In one characteristic of the HOPD lab scheme, hospitals generally are in-network providers for health insurance plans and typically have higher reimbursement rates than those of independent lab companies. Thus, if the lab companies can have the participating hospital send their lab test claims along with the in-network hospital's lab test claims, their lab test claims can get higher in-network payment rates.

"In this way, the defendants used the Newman Hospital to disguise allegedly fraudulent healthcare claim forms, which misrepresented that laboratory testing services were performed at Newman Hospital, when in truth, the testing was not done there," court documents showed. "Indeed, defendants completed, or caused to be completed, the laboratory tests at issue for patients from around the country, including here in Pennsylvania, who had no contact at all with Newman or its physicians. Then, defendants fraudulently submitted claim forms to Aetna misrepresenting that the tests had been performed at Newman, by Newman, and for Newman patients."

In the Newman Hospital case, Aetna's lawsuit charged that defendants exploited the fact that Aetna had an in-network contract with the hospital requiring Aetna to pay the hospital significantly more for lab

services provided at the hospital than Aetna would pay for out-of-network claims. The defendants disguised the out-of-network labs as Newman Hospital claims, the lawsuit explained. "Defendants thereby submitted or caused the submission of more than 10,000 false claim forms, which induced Aetna to pay millions of dollars at the Newman network contract rate," the court documents showed.

$21M Billed Over 16 months

Over 16 months, the defendants generated more than $21 million in payments from Aetna, the lawsuit alleged. "Defendants funneled these monies through Newman and diverted the funds to themselves, leaving Newman teetering on the brink of insolvency," court documents showed.

To show the extent of the alleged fraudulent activity, court documents explained that in the year before the fraud was committed, each month, Aetna paid Newman Hospital an average total of about $1,300 for 72 lab claims. But after the defendants took control of Newman Hospital's billing, Aetna paid Newman approximately $1.35 million per month for more than 10,000 lab claims over 16 months, the lawsuit charged. Of that $1.35 million, the defendants took all or most of it, the lawsuit added.

In its lawsuit, Aetna said this conduct constituted fraud, based on the misrepresentations that the lab services were performed and processed by and at Newman Hospital, when they were not. "Pursuant to contracts that certain defendants caused Newman to enter with other defendants operating the labs, those labs received at least 60% to 70% of the money that Aetna paid Newman as a result of the fraudulent claims, while the large part of the remainder was divvied up among the other defendants," the lawsuit explained.

In an effort to get comments from the defendants, THE DARK REPORT contacted the attorneys listed in court filings. There was no response by press time. TDR

—Joseph Burns

Same Lab Defendants Named In Different Payer Lawsuits

IN THE AETNA LAWSUIT, THE DESCRIPTION of the alleged HOPD lab test fraud scheme is similar to that of an earlier lawsuit that a health insurer in Mississippi filed, and several of the same lab companies are named as defendants in both lawsuits.

On May 4, 2017, **Blue Cross & Blue Shield of Mississippi** filed a lawsuit in the U.S. District Court for the Southern District of Mississippi against a small community hospital and several lab companies. Named as defendants were:

- Sharkey-Issaquena Community Hospital
- Sun Clinical Laboratory, LLC;
- Mission Toxicology Management Company, LLC;
- Mission Toxicology, LLC;
- Mission Toxicology II, LLC; and,
- 10 unnamed "John Does."

The 29-bed hospital is located in Rolling Fork, Miss., with a population of 2,500. The other defendants are based in Texas. *(See TDR, June 5, 2017.)*

In court documents, BCBS charged the hospital and the lab companies with breach of contract, fraud, civil conspiracy, negligent misrepresentation, and unjust enrichment. The lawsuit said that, "between February and May 2017, the [25-bed rural] hospital submitted to the insurer claims totaling in excess of $33.8 million."

The lawsuit alleged that, "since February 2017, claims were submitted to Blue Cross for payment for laboratory services that: 1) purported to have been performed at and by the hospital; 2) were not ordered by a licensed health professional with appropriate staff privileges at the hospital; and, 3) were not performed at the hospital in Rolling Fork."

Three of these defendant lab companies—Sun Clinical Lab, Mission Toxicology, and Mission Toxicology Management—are also named as defendants in the Aetna lawsuit filed in Pennsylvania on Sept. 29.

Big Mergers Dominate Healthcare Headlines

CVS buys Aetna, UnitedHealth buys DeVita, Dignity to Merge with Catholic Health Initiatives

CEO SUMMARY: Since Dec. 3, four unexpected megamergers became national news. Pharmacy chain CVS Health acquired Aetna. Advocate Health Care and Aurora Health Care will merge. UnitedHealth Group purchased the 2,000 physicians of DaVita Medical Group. Dignity Health and Catholic Health Initiates decided to create a super-hospital system with 139 hospitals in 28 states. Clinical labs and pathology groups serving any of these entities will want to watch developments closely.

FOUR LARGE AND UNEXPECTED MEGAMERGERS involving healthcare enterprises were announced within days of each other earlier this month. Each transaction represented a significant development that has the potential to reshape how healthcare is delivered in the United States.

Once completed, these mergers could have a significant effect on clinical laboratories and pathology groups. Below is a summary of the acquisitions, followed by analysis of each transaction.

CVS to Acquire Aetna

This deal was announced on Dec. 3. **CVS Health**, a national pharmacy chain, is acquiring health insurer **Aetna** for $69 billion. The transaction requires regulatory approval.

Advocate, Aurora to Merge

The next day, Dec. 4, Chicago-based **Advocate Health Care** and Milwaukee based **Aurora Health Care** said they would combine operations. This would create the 10th-largest nonprofit system with $11 billion in annual revenues and 27 hospitals.

UnitedHealth to Acquire DaVita Medical Group

On Dec. 6, **UnitedHealth Group** announced an agreement to acquire **DaVita Medical Group** from dialysis provider **DaVita Inc**. The health insurer will pay $4.9 billion.

Dignity Health, CHI to Merge

A day later, on Dec. 7, **Catholic Health Initiatives** (CHI) and **Dignity Health** stated that they had a definitive agreement to merge into a new nonprofit system. When completed, the merger would create the nation's largest nonprofit hospital system, with revenue of $28.4 billion.

Was Amazon.com A Factor?

News that CVS Health had an agreement to acquire Aetna of Hartford, Conn., caught the healthcare industry by surprise. Analysts speculated that what motivated CVS to move in this direction were reports in the fall that **Amazon.com** of Seattle received approval for wholesale pharmacy licenses in at least 12 states. Amazon.com has a track record of entering industries and causing prices to fall.

CVS owns **CVS Caremark**, a pharmacy benefits management company. Analysts are studying how the acquisition of Aetna can help CVS protect its pharmacy benefit management business from possible inroads by Amazon.com.

In *Forbes*, Bruce Japsen reported that one result of the CVS-Aetna merger would be a strong effort to keep patients out of the hospital. Instead, the two companies would aim to deliver as much care as possible outside of hospitals, while moving away from fee-for-service medicine and toward value-based care.

CVS plans to expand services in its pharmacies and retail clinics, and even deliver care to customers' homes, Japsen wrote. "This is bad news for the nation's hospitals, which still see millions of patients in their emergency rooms and provide care for ailments that CVS and Aetna executives say could be avoided or directed to an outpatient location," he added.

CVS operates 10,000 pharmacy and clinic locations, which Aetna could use to provide care directly to customers, *The New York Times* reported.

UHC Adds 2,000 Doctors

In the case of UnitedHealth's acquisition of DaVita Medical Group, the health insurer will be adding a medical staff of more than 2,000 physicians to the approximately 30,000 doctors already working for, or affiliated with, UnitedHealth's health services business, **Optum**.

The acquisition of the DaVita Medical Group fits right into UnitedHealth Group's plan to direct patients from high-cost hospital settings to lower-cost urgent care and outpatient facilities, commented Michael J. Baker, an analyst with **Raymond James**. The deal will allow UnitedHealth Group "to leverage its vast physician footprint to accelerate that change," Baker added.

Once the planned merger of Dignity Health of San Francisco and Catholic Health Initiatives of Englewood, Colo., happens, it will create the largest non-profit hospital system by operating revenue, according to *The New York Times*. This system would have 139 hospitals in 28 states and have combined revenue of $28.4 billion. It would employ more than 159,000 employees and 25,000 physicians.

One interesting aspect to this merger is that, once the two companies are combined, the resulting health system would have operations in 28 states with no overlap in hospital service areas. Executives at the two health systems believe this could help expand patient access. They also think this would also help to gain regulatory approval for the merger.

Nation's Biggest Systems

The next largest non-profit hospital organization would be **Ascension Health**, which has $22.6 billion in revenue. The nation's largest integrated health system is **Kaiser Permanente**, which had $64.6 billion in revenue last year.

This merger is particularly important to CHI, which has struggled financially. Once it is part of Dignity Health, CHI could refinance debt based on Dignity's higher credit rating, the Times reported. In an announcement, the companies said outpatient care and virtual care would bring providers closer to patients' homes while broadening clinical programs for patients with chronic illness.

Rethinking Strategies

These four megamergers are evidence of how the health systems is forcing even the nation's biggest players to rethink their clinical and business strategies. Clinical lab administrators and pathologists can expect to see more acquisitions and mergers that will combine companies in unexpected ways. Each of these megamergers will have the potential to change certain contractual relationships companies and health plans have with clinical labs. TDR

—Joseph Burns

Misinterpreted Gene Test Shows Lab Got it Right

In unusual twist, lawyer praises genetic test lab in $1.8 million medical malpractice case

CEO SUMMARY: It's almost a case of man bites dog. In malpractice cases involving genetic test results, labs are often assumed to be at fault. But in a lawsuit filed in Oregon, health-care providers are alleged to have misinterpreted a genetic test. As a consequence, a patient underwent medically-unnecessary and life-changing surgery. This malpractice lawsuit has several elements of interest, particularly for pathologists and lab managers who perform genetic tests.

WHEN A LAWSUIT IS FILED OVER THE interpretation of a genetic test, there's an inherent assumption that the clinical lab is responsible in some way. That assumption of error is what makes a recent case in Oregon so unusual.

In this malpractice lawsuit, the lab that performed the genetic test was recognized as having accurately reported the results to the ordering physician. The lawsuit alleges that the primary care provider and the specialist physician both misinterpreted the genetic test report.

Genetic Test Complexity

This case is an example of how the complexities of genetic testing can be confusing to physicians who order these tests and then must interpret the results when deciding how to diagnose and treat their patients. In the lawsuit, filed in October in Curry County Circuit Court, 36-year-old Elisha Cooke of Gold Beach, Ore., is suing her doctors after genetic tests were negative for breast cancer.

In its report to the patient's doctor, **Myriad Genetics** tested the patient's blood sample using its Integrated BRACAnalysis with Myriad myRisk Hereditary Cancer test on Feb. 18, 2016.

Court documents show that, when Myriad sent the lab test report to Cooke's doctor, William Fitts, MD, an obstetrician and gynecologist in Gold Beach, Ore., the report clearly stated the result as: "Negative—No clinically significant mutation identified."

Despite this result, Cooke's attorney, Chris Cauble said, "Her gynecologist, Dr. William Fitts, ordered the test and misinterpreted the results. We will be amending the claim in the suit to make that clearer. The medical documents we have reviewed were not clear on this point but they are clearer now.

"Originally, we thought that the nurse practitioner, Lori Johns, ordered the test and initially interpreted it," added Cauble of **Cauble, Cauble and Selvig** in Grants Pass, Ore. "It was, in fact, her gynecologist, Fitts.

"The other physicians either failed to independently check the results or they also misinterpreted them," he added. "Johns is

my client's primary care provider. As a licensed nurse practitioner in the state of Oregon, she is required to provide follow-up care and also review test results, to ensure that the patient gets the right care.

Misinterpreted Results?

"This actually makes it more shocking because it was an actual, experienced MD who misinterpreted the results," Cauble explained. "I want to make sure we are super accurate on that point."

After reviewing the test results, Cooke's doctors recommended a double mastectomy. In August 2016, Cooke had a total abdominal hysterectomy and less than two months later had a prophylactic bilateral nipple-sparing mastectomy with placement of implants.

The lawsuit states, "Plaintiff would not have consented to these procedures if she had known that Lynch Syndrome does not cause a significant increase in the risk of breast cancer." Remarkably, the lawsuit does not name Myriad. "So far, we are not concerned with how Myriad conducted the test," stated Cauble.

This case offers lessons for clinical lab managers and pathologists seeking to avoid liability when physicians' actions following genetic testing result in patient harm. For all clinical labs, the lesson is: make the test results as clear as possible. In this case, the report from Myriad provided clear results that unfortunately were unheeded.

"Myriad did the myRisk Hereditary Cancer test, and the test results are clear," Cauble said. "Our client didn't have any significant genetic issues that would have indicated any kind of cancer abnormalities."

Test Interpretation Was Key

In fact, the report included the mathematical sign for negative (a solid horizontal line inside a circle as on the negative end of a common household battery). In addition to the wording, "Negative—No clinically significant mutation identified," Myriad explained further, "Note: 'Clinically significant,' as defined in this report is a genetic change that is associated with the potential to alter medical intervention."

"Based on the records we have discovered, it was first the gynecologist who misinterpreted the report," Cauble explained. "However, there was no safeguard in the system for ensuring he was accurate. As is common in Oregon, Cooke's PCP is a nurse practitioner. We believe that there should have been better safeguards. I also want to point out that her surgeon also had a duty to review and interpret the report and provide proper advice to Cooke."

Yet, the patient's physicians recommended surgery, as the court documents show. "The doctor seems to be relying on the part of the report that says there are variants of uncertain significance in the MLH1 gene," Cauble added. "The genetic testing lab says that in certain patients, variants associated with the MLH1 gene can mean there is an increased cancer risk."

Two Variants Identified

The report identified two variants on the MLH1 gene, but, again, the report identifies the two variants and then is clear about what the variants mean for this patient. "Uncertain clinical significance," the report says about the MLH1 variants. "There are currently insufficient data to determine if these variants cause increased cancer risk."

Variants on the MLH1 gene can be associated with Lynch syndrome, ovarian, and other cancers. The Myriad report does not mention these possibilities, saying only that the variants are of uncertain significance.

Given the clarity of the report, the physician should have recommended other actions, Cauble added. "Despite the clear language in the report, we think the physician's advice to my client that she have her breasts removed and her uterus removed is a breach of the physician's duty," he

Malpractice Lawsuit Says Genetic Test Results Were Misinterpreted, Never Reviewed

IN A LAWSUIT FILED ON BEHALF of an Oregon patient, the details of how a misinterpreted genetic test result led to two unnecessary surgeries is explained.

In August 2015, Elisha Cooke had an annual exam and Pap smear with Courtney P. Ridley, MD, an obstetrician and gynecologist, court records show. Ridley "noted the plaintiff [Cooke] needed an assessment for a Lynch Syndrome or breast cancer gene test, and ordered both a mammogram and 'BRCAl' and 'BRCA2' testing," the lawsuit states.

"Lynch Syndrome is a genetic condition associated with increased risks and earlier onset of colorectal, endometrial, ovarian, and other cancers. There is no increased prevalence of breast cancer with respect to Lynch Syndrome," the lawsuit adds.

Later that month, Cooke had a mammogram and the results were negative, revealing no suspicious mass or calcification. In December, Lori A. Johns, a nurse practitioner who worked for **Curry Community Health**, referred Cooke to William Fitts, MD, an obstetrician-oncologist, for further examination relating to breast cancer. Fitts incorrectly interpreted Cooke's genetic test results and misreported that she had the MLH1 gene mutation and Lynch Syndrome, Cooke's attorney, Chris Cauble told THE DARK REPORT.

In January 2016, Fitts evaluated Cooke, noting that her Pap smear, mammogram, and CA-125 test results were normal or benign and ordered BRCA1 and BRCA2 tests.

"On or about February 18, 2016, Plaintiff's BRAC1 and BRAC2 tests reported negative with no clinically-significant mutations," the lawsuit says. "Despite the fact the screening and genetic testing results were negative, defendants continued to misdiagnose plaintiff as positive for Lynch Syndrome and the MLH1 gene mutation."

In April, the lawsuit states, the defendants incorrectly determined that Cooke had "Lynch Syndrome cancer genes" and thereafter entered those same words into plaintiff's care assessment and plan. "Defendants continued to negligently rely upon the misinterpreted genetic testing results," the lawsuit says. "Defendants continued to negligently rely on the misdiagnosed Lynch Syndrome testing results, and further, operated under the mistaken belief that Lynch Syndrome would make plaintiff more likely to have breast cancer."

As a result of the defendants' negligence, Cooke believed she had Lynch Syndrome, and, as a result, was more likely to get breast cancer, the lawsuit states. During a later evaluation, the defendants recommended a mastectomy and referred Cooke to a surgeon in Medford, saying, "AllCare is willing to pay for the reconstruction." AllCare is the health insurer under contract to Oregon Medicaid.

In August 2016, Fitts noted that Cooke had Lynch Syndrome and that she was positive for the MLH1 gene variant, which he advised was "one of the mutations is associated with Lynch syndrome," and that "her lifetime risk of breast cancer is at least 50%, ball bearing cancer 60% to 70%, and endometrial cancer may be as high as 80%," the lawsuit states.

Fitts' conclusions were not supported by the genetic test results, and Fitts did not have a reasonable basis to associate Lynch Syndrome with an increased risk of breast cancer, the lawsuit states.

"Defendant Fitts performed a total abdominal hysterectomy on plaintiff on or about August 24, 2016. Plaintiff would not have consented to these procedures had she known that she did not have Lynch Syndrome. Plaintiff would not have consented to these procedures if she had known that Lynch Syndrome does not cause a significant increase in the risk of breast cancer," the lawsuit says.

Less than two months later, Cooke had a prophylactic bilateral nipple-sparing mastectomy with placement of implants.

explained. "At least, he should have told her about the fact that the results of the test were negative and that no clinically significant mutation was identified.

"So far, it looks like Myriad did a good job and is handling this well," Cauble said. "Based on the evidence so far, we don't have a problem with them. The result is clear and easy for anyone to understand." *(See sidebar on page 21.)*

"Our position is that, based on this lab test report, the physician should have recommended the patient at least see a genetics specialist," Cauble said. "But instead, the physician did the surgery based on this result and that's what our case is about. Not only that, they botched her breast removal surgery, complicating the case still further."

As a result of the botched surgery, Cooke sought an attorney and met with Cauble, he said. "She didn't find out about her negative test result until after I recommended she see another surgeon about her surgical options," he explained. "That surgeon saw that the genetic test result was negative. When the second surgeon informed Cooke about the negative genetic test result, it was the first time she heard this news," Cauble said.

"At that point, she was quite shocked and upset and called Myriad to confirm that the test was negative," Cauble added. "Myriad did a great job. I don't have any problem with them. The genetic test result is very clear."

One Error Gets Compounded

So, who is responsible for informing the patient about her genetic lab test results?

"There is no indication that the physician ever called the lab," Cauble answered. "If he had, the lab would have told him that the test was negative. Instead, he seems to rely on the fact that the patient has a family history of cancer. In addition, the nurse practitioner had entered in the patient's record that Cooke had Lynch syndrome.

Cooke has a family history of invasive breast cancer and endometrial or uterine cancer, the Myriad report notes. "However, based on the personal/family history, the patient's cancer risk may still be increased over the general population," the report says.

Test Results Need Clarity

Given that the surgeries were elective, Cauble questioned why the patient's insurer, **AllCare**—which contracts with Oregon Medicaid—would have paid for these procedures without inquiring about the medical necessity. Cooke was covered under Oregon's Medicaid program, he added.

In the lawsuit, Cauble seeks the maximum of $1.8 million allowed under Oregon law. "We may be making an argument that the amount we are entitled to should be higher," Cauble said. "Currently, claims against 'hospital districts' and their employees are limited to just under $800,000 per person, per claim. The nurse practitioner Johns works for a private clinic so that cap would not apply to her.

"However, there is also a $500,000 cap on non-economic damages that would relate to Johns because she works for a private entity," he added. "Actually, we are thinking of making three independent, $800,000 claims based on three different mistakes by three people."

The lawsuit lists the defendants as the **Curry County Health District**, Curry Community Health, **Curry Medical Practice**, and **Curry Medical Center**. The lawsuit list other defendants as Fitts, Johns, and a surgeon, Jessica Carlson, MD.

The medical practice's CEO and Fitts' attorney told *CBS News* that they could not comment on pending litigation. An attorney for Carlson told *The Washington Post* she could not comment on pending litigation. **TDR**

—Joseph Burns

Contact Christopher Cauble at 541-476-8825 or ccauble@thecaublefirm.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

To deal with a shortage of surgical pathologists in the United Kingdom, the British **National Health Service** (NHS) is looking at solutions, such as deployment of digital pathology systems. According to a story in *Pharma Times*, the NHS is negotiating with **Roche Diagnostics** and partners to develop a program to implement digital pathology systems across the National Health Service, adding that the NHS will invest in acquiring and using whole slide scanners, image management software, and image analysis algorithms.

MORE ON: *Digital Path*

The NHS hopes that use of digital pathology systems will help it improve access to pathologists and other experts and to provide timely and accurate diagnosis for cancer patients. *Pharma Times* stated that a shortage of anatomic pathologists in the UK and geographic constraints make it difficult and time-consuming for experts to provide an opinion on cancer cases. For pathologists watching the pace of adoption of digital pathology and whole slide images, the reference to image analysis algorithms will be of interest. Because of the need to make its pathologists more productive, the NHS may want to accelerate development and clinical use of image analysis algorithms. In turn, clinical data gathered in the use of such algorithms in the U.K. could be used to speed up regulatory review of these same algorithms in the United States.

AURORA ACQUIRES CBM PATHOLOGY

Aurora Diagnostics of Palm Beach Gardens, Fla., announced Dec. 1 that it acquired Gaithersburg, Md.-based **CBM Pathology**, a five-physician anatomic pathology and cytopathology specialty practice founded in 1999. Terms of the CBM transaction were not disclosed.

TRANSITIONS

- **Joint Venture Hospital Laboratories** (JVHL) of Detroit, Mich., reported that Jack Shaw, its co-founder and long-time executive director, died on Nov. 30. Shaw served at JVHL from its founding in 1992 until his retirement in 2012. During his career, he held executive positions with **Oakwood Health System**, **HomeCare of Michigan**, and **MedNet Services**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...a new photoacoustic imaging technology based on light and sound that can accurately detect the margins of a tumor during surgery. The new device was developed by researchers at **Washington University School of Medicine in St. Louis** (WUSTL) and **California Institute of Technology** (Caltech).

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, January 2, 2018.