Volume XX, Number 7 Tuesday, May 28, 2013

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

Financial Hurricane Hits Entire Lab Testing Industry

FOR ABOUT 18 MONTHS NOW, THE ENTIRE LABORATORY TESTING INDUSTRY has been hit by an ongoing series of painful cuts to lab test fees and announcements of more restrictive coverage guidelines.

Even today, there is additional news of rock bottom prices to share with you. In this issue, you'll read about **Aetna, Inc.'s** latest strategy to reduce what it spends on lab testing. Pathologists, for you, the news is a global 88305 fee of just $35.05! Clinical lab managers, your news is an 80053-Comprehensive Metabolic Panel reimbursed by Aetna at $6.54 and an 85027-Complete CBC Automated for which it will pay just $4.00. These prices take effect on July 1, 2013. *(See pages 16-18.)*

It this a smart move by Aetna? I think not. It is unlikely that routine chemistry panels and CBCs are the primary source of the year-over-year increase in what Aetna and other payers spend on lab testing. Assuming that to be true, could slashing prices for routine assays down to the level of marginal cost prove to be rapidly disruptive to physicians who rely on timely, accurate lab tests to provide patient care that delivers ever-better outcomes? Time will provide that answer.

In the meantime, lab administrators and pathologists must consider the consequences of Aetna's latest price-cutting effort. They cannot view the Aetna pricing in isolation. That is, if labs accept the Aetna pricing, are they foolish enough to believe that **UnitedHealthcare**, **WellPoint**, **CIGNA**, **Humana**, and other payers are not going to come after them for further price concessions? It would certainly be wise for lab industry associations and professional groups to quickly band together and firmly oppose this latest attempt by a major national health insurer to cram money-losing reimbursement rates on the entire lab industry.

I don't think it is an overstatement to say that the laboratory testing industry is currently beset by a major hurricane of lab test price cuts. At every turn, there is at least one major payer doing one of three things: 1) excluding laboratories as providers from its network; 2) issuing coverage guidelines that restrict beneficiaries' access to certain lab tests; and, 3) arbitrarily dropping the price it pays for significant types of lab tests by substantial amounts.

It is essential that lab leaders step forward and fight the battle to maintain fair and adequate reimbursement for the laboratory tests that underpin much of the essential healthcare in this nation. TDR

Much Uncertainty About Pay for Molecular Codes

Medicare contractors posting prices that are 40% to 50% less than what labs received in 2012

CEO SUMMARY: Having gone unpaid since January 1 for the 114 new molecular CPT codes, many clinical labs and pathology groups have stopped running these tests or laid off staff. Some are considering closing their doors. Evidence indicates that certain Medicare contractors are deciding that some molecular tests are not medically necessary. Medicare officials launched the 60-day comment period on May 9, which gives labs until July 8 to submit comments about pricing and coverage decisions.

FIVE MONTHS INTO THE NEW YEAR and two things remain true about implementation of the 114 new Tier I and Tier II molecular pathology CPT codes, neither of which can be seen as positive for the clinical laboratory profession.

First, with almost half of the current year already gone, clinical labs and pathology group practices remain unsure about when they will be paid for the large and growing number of their molecular test invoices submitted to Medicare Administrative Contractors (MACs) and many private health insurers since January 1, 2013.

Second, reimbursement rates for the new molecular CPT codes recently posted by MACs are significantly less than what labs were being paid under the previous code-stacking arrangement. The Medicare program has started the clock on the required 60-day comment period as a necessary step to implement these prices.

As of late May, few laboratories report receiving payment for these molecular CPT codes. At the same time, some Medicare contractors are continuing to set prices for 114 new molecular test codes that became effective on January 1.

On May 9, one MAC, **Palmetto GBA**, said it would finalize rates by May 15. Previously, the federal **Centers for Medicare & Medicaid Services** (CMS) had said all MACs were supposed to have submitted their proposed rates for the 114 tests to CMS by April 1, and CMS was supposed to post those rates by April 30.

As of May 15, only two MACs had done so: Palmetto and **Cahaba GBA**. The remaining Medicare contractors were still setting prices and some MACs may

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

choose not to set rates for certain codes. These Medicare contractors believe tests falling under these codes to be investigational, experimental, or non-eligible for Medicare coverage for other reasons, such as screening, which is not a covered Medicare benefit.

As well, certain MACs are not setting rates for codes for which they did not receive any claims. The MACs have said they would not make payments to labs submitting claims without first setting prices for the new molecular CPT codes.

Labs Are Cutting Staff

"As a result of not being paid for many of their molecular tests done since January 1, clinical labs are discontinuing molecular testing, laying off staff and some lab companies may be forced to close," stated Kyle Fetter, Associate Vice President of Molecular Diagnostic Services at **XIFIN, Inc.**, a revenue management company in San Diego, California.

Perhaps most concerning is that Medicare contractors have decided that some of the new molecular tests are not medically necessary. This unwelcome development is seen as setting back the movement toward personalized medicine.

"When labs don't get reimbursed for certain tests, they will either decide not to run those tests or they will seek to charge patients directly," Fetter said. "Also, if labs remove those tests from their test menus, that's bad for patients—but also it means that development of those tests has stopped.

"When payers make the decision that some of these tests are medically unnecessary, that will have a chilling—but as yet unmeasurable effect—on the innovation needed to develop new molecular tests," explained Fetter. "A meaningful number of AMA members have expressed frustration that tests that had been important to the doctors and their patients and covered previously, are now being denied by many payers, including Medicaid.

"Since April 15, when Palmetto and Cahaba published rates for most of the 114 tests, more Medicare contractors have published prices, but not all have done so," continued Fetter. "Of the rates that have been published, XIFIN estimates that most are about 40% lower than what the Medicare contractors paid molecular labs for the same tests last year."

"On May 20, **NHIC** updated its molecular test prices," stated Genevieve Tang, Associate Director of Strategic Product Planning for **Quorum Consulting** in San Francisco, California. "But these prices did not reflect the rates included in the payment file that CMS released on May 9.

"The key point here is that some MACs are continuing to update their fee schedules outside of CMS' 60-day comment period," she added. "This gives labs an opportunity to continue engaging the MACs during this period." NHIC serves providers in Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.

"Not many payments for these molecular CPT codes have gone through yet, in part because there are still quite a few Medicare contractors who continue to make decisions about pricing," Fetter said. "We understand, for example, that **Noridian**—one of the largest Medicare contractors—is just now starting to issue checks." Noridian serves providers in Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming.

Priced 22 Of 114 CPT Codes

"Most Medicare contractors have priced more than 70 of the 114 new CPT codes and some contractors have priced almost all of the codes," explained Fetter. "In the case of **NGS**, another large Medicare contractor, we have heard that it is not paying yet and has priced only 22 of the 114 codes." NGS serves New York and Connecticut.

According to Fetter, the molecular pathology fee schedule NGS made public

New Medicare Molecular Test Payment Rates Are 40%-50% Lower Than What Was Paid Last Year

PRICES POSTED FOR MOST of the new 114 Tier I and Tier II molecular lab test codes are about 50% to 60% lower than what labs were paid for those same tests last year, according to an analysis by XIFIN, Inc., a company that specializes in revenue management for labs.

"Right now, pricing in aggregate—meaning what prices labs will get based on the prices published so far and not counting the denials—represents a 50% to 60% discount over what they got paid under the stack codes last year," stated Kyle Fetter, Associate Vice President of Molecular Diagnostic Services at XIFIN.

"Here's an example. Take the EGFR test, which is common and a highly useful test," said Fetter. "The **Qiagen** kit for this test was reimbursed last year at about $1,000 to $1,700—depending on the lab procedure used under the stack codes.

"Currently, Palmetto GBA has posted a price of $225 for the EGFR test under the current Palmetto fee schedule," continued Fetter. "At $225, Palmetto is offering a discount off the stack code rate of 75% to 80%.

"Stack codes were a method of pricing molecular tests that labs and payers used through the end of last year," added Fetter. "The new pricing system the Medicare contractors are using this year is designed to replace the stack codes. The new molecular CPT codes were created to enable payers to know what test was run by the laboratory submitting the claim.

"Frankly, the cost of a Qiagen kit is roughly around $200 and that's before the lab pays for the reagents, shipping, transport, technician labor, lab overhead and other costs needed to perform this test," Fetter explained. "For a test like that, lab costs would total about $450 to $700. Labs will lose money on this very common test if they get paid just $225 for the EGFR test.

"There are similar pricing issues with the BRAF, KRAS, and other tests on Tier II of the new molecular tests, such as CYP450 3A4 and 3A5," Fetter added. "For these tests, the announced prices represent a reduction of 40% or more, which is a very dramatic reduction in the amount of money labs receive for performing these molecular diagnostic tests."

is a simple spreadsheet listing 22 prices for 22 CPT codes. There is no explanation about the remaining 92 codes.

"We heard that NGS reported to a number of labs that some of the molecular CPT codes that have not been priced are not medically necessary," noted Fetter. "If true, then essentially NGS is saying that, of the 114 molecular codes available now, representing 90% of the most commonly ordered molecular diagnostic tests in prior years, it considers that there are only 22 that should be priced."

To Fetter's knowledge, none of the Medicare contractors has posted prices for all of the 114 new molecular CPT codes. "But setting prices for only 22 tests—as NGS did—is an unexpectedly low number," observed Fetter.

"The information we are hearing is that—by not setting prices on certain tests—the Medicare contractors are saying these tests are not medically necessary," he added. "Labs should keep in mind that no one knows what effect a Medicare contractor's decision may have on the future use of these tests.

"On the issue of medical necessity, NGS is not alone," explained Fetter. "Some of the other Medicare contractors have said they believe some tests are not medically necessary.

"That is a surprisingly negative stance and could have important consequences," he continued. "For example, when one Medicare contractor decides not to cover these tests, it means those tests are not available to Medicare patients and their physicians in that jurisdiction.

"This creates a huge discrepancy in medical care from one Medicare jurisdiction to the next," noted Fetter. "How can the Medicare program, which is designed to serve patients nationwide, justify that disparity? In each Medicare jurisdiction nationwide, patients and their physicians rely on these molecular tests."

CMS is asking labs to comment on the contractors' prices. Clinical labs and pathology groups have 60 days—until July 8—to do so. But not all contractors have issued prices and those that have published prices have not disclosed the methodology by which those surprisingly low prices were established. This makes it difficult for labs to comment.

Even though prices from the various MACs vary widely, Tang said, "We have observed that Noridian, **CGS**, **Novitas**, and **WPS** used Palmetto's payment rates for nearly all of the MoPath codes, and, with a few exceptions, NGS and NHIC essentially have the same fee schedules."

MACS Operate Independently

The problem for laboratories is they have to respond to CMS about what the Medicare contractors are doing and labs don't have a unified message since each MAC operates independently, Fetter said.

"Because each Medicare contractor is making its own coverage and pricing decisions, it is extremely difficult for labs to comment," noted Fetter.

"Also, having each Medicare contractor set prices on its own could put some labs at a severe competitive disadvantage," he continued. "In one jurisdiction, a lab might get a much lower rate of payment for a test than another lab gets for the same test in another jurisdiction.

"The laboratory that gets the lower rate can be at a significant disadvantage," noted Fetter. "This is especially true when you consider that the difference in payment might be $900 in one jurisdiction but only $200 in another."

Seeking Consistency

On May 9, CMS sought to ensure consistency by suggesting that all Medicare contractors adopt Palmetto's prices as their own. "What we're seeing is that some of the contractors, such as Noridian and CGS, are implementing prices based on Palmetto data," commented Fetter. "However, contractors in other jurisdictions—such as NGS—seem to have ignored the suggestion from CMS to use Palmetto's prices.

"During 2012, Palmetto was the only contractor to prepare to set prices and pay for these 114 molecular tests," he noted. "As a result of collecting data from clinical labs on molecular test pricing and the utility of molecular tests, Palmetto was in the best position of all Medicare contractors to set prices for these new molecular CPT codes.

"This whole issue of molecular test pricing and payment is really astounding when you consider how badly it's been handled," opined Fetter. "What once looked like a series of poor decisions made within the Medicare program last year has continued to drag on.

"Labs are asking themselves, 'What are our options now?'" he emphasized. "Labs are facing very difficult questions today and they are not getting any timely or constructive answers from their Medicare contractors.

"Exacerbating the problem, private payers are beginning to adopt some of the incoherent Medicare contractor pricing for molecular tests," he said. "This adds to the financial stress on the innovators of this new healthcare technology." TDR

—Joseph Burns

Contact Genevieve Tang at 415-835-0190 or genevieve.tang@quorumconsulting.com; Kyle Fetter at 858-793-5700 or kfetter@xifin.com.

Health Insurers See Big Increase in Lab Utilization

Spending on clinical lab testing growing at twice the rate of spending on all other care

CEO SUMMARY: In a recent public workshop, managed care executives revealed that the annual cost of outpatient laboratory testing is increasing at twice the rate of all other medical services. One big driver in the increased spending on lab testing is increased utilization of lab tests by physicians—particularly expensive molecular diagnostic assays and genetic tests. This trend is one reason why private health insurers are taking steps to control the year-over-year increase in the cost of lab testing.

IN THE STRUGGLE TO CONTROL the year-over-year increase in spending on clinical laboratory testing, both government and private payers have recently become quite aggressive at instituting ways to drive down laboratory testing costs.

This trend was the topic of a special two-hour workshop at the *Executive War College* in New Orleans earlier this month. A panel of four experts in different aspects of managed care contracting for laboratory testing services participated and offered observations and recommendations about this important subject.

Understanding Payers' Views

The views of two panelists are presented in this intelligence briefing. One panelist was Linda Stewart, the Vice-President, National Lab Program at **UnitedHealthcare**. She gave attendees a macro-view of how the nation's largest private health insurance company views the most important trends in both healthcare and laboratory testing.

The second panelist was Trisha Brown, MS, LCGC, a genetic counselor and founder of **Shama Consulting**. She was formerly Vice President of Clinical Operations for **DNA Direct**. Brown discussed why government and private payers are taking steps to institute pre-authorization for expensive molecular assays and genetic tests.

Both of these speakers provided perspectives from the health insurer's side of the table. These are insights not commonly made public and are useful in helping lab executives and pathologists better understand the financial and clinical issues confronting health insurers on the subject of clinical laboratory testing and molecular diagnostics.

In her remarks, Stewart gave attendees a highly useful perspective on how a major national insurance company views the healthcare marketplace. She noted that at UnitedHealthcare, laboratory testing costs are rising at a faster rate than overall medical costs are rising.

Other panelists during this session confirmed that the year-over-year increase in lab testing costs are also a concern at both **Aetna, Inc.**, and **WellPoint, Inc.** Each of these companies is taking a different approach to control the cost of lab testing. *(See "Aetna to Lower Test Prices, Effective July 1," page 16.)*

Stewart provided context for lab testing at UnitedHealthcare. "Our national lab program serves about 40 million members," stated Stewart. "Most concerning to us is the fact that spending for outpatient lab services is rising at a faster rate than our spending for overall medical care is rising.

"In an attempt to understand what is driving that increase in spending, we looked closely at the numbers," she continued. "We determined that unit costs [average cost per test] were not the driving factor. Instead, most of the increase in what is spent on laboratory testing comes from increases in utilization.

More Molecular Testing

"For example, molecular diagnostic testing and drug testing—including therapeutic drug monitoring—are areas where utilization is rising most rapidly," noted Stewart. "The utilization growth for drug testing resulted in significant spending increases over the most recent three-year period.

"UnitedHealthcare is responsible to its customers and consumers for how it manages their healthcare dollars," noted Stewart. "When utilization rises quickly like that for any type of clinical service, then we ask our network providers to do what they can to control this rising utilization.

"One way UnitedHealthcare manages utilization is by sharing risk or savings with providers, such as in accountable care organizations (ACOs)," she explained. "In the past, we had fee-for-service contracts with providers. Today, we are collaborating with physicians and hospitals on performance-based contracts."

This is a notable development. It is consistent with THE DARK REPORT's analysis that clinical laboratories and pathology groups will begin to see less pure fee-for-service contracts in favor of contracts with payers that include value-based reimbursement arrangements.

"In these contracts, UnitedHealthcare works with physicians to agree on performance metrics," said Stewart. "Certain of these metrics relate to the use of lab tests. We ask our physicians to use network labs. Then we measure their performance against that standard."

Following Stewart's comments in the panel discussion, Trisha Brown addressed the reasons why payers are implementing procedures to ensure that physicians order the appropriate assays for patients seeking genetic testing. Brown explained that physicians often order inappropriate genetic tests for their patients.

DNA Direct is a division of **Medco Health Solutions**, a benefit manager for large employers. Brown worked with Medco's employer and hospital clients.

"Utilization of genetic tests for inherited cancers illustrates the challenge in helping physicians utilize these tests appropriately," stated Brown. "For example, our studies showed that, when a physician was ordering a test based on a prior indication of cancer in a patient's family history, the genetic testing was inappropriate about 60% of the time!

"It was inappropriate because the physician didn't get the full family history or didn't understand it," she explained. "If the physician saw any history of breast cancer in a patient's family, the doctor would order the BRCA1 or BRCA2 tests.

Ordering Inappropriate Tests

"But about 40% of the time, the family history showed that the patient was not at risk for the BRCA syndrome," Brown noted. "Instead, these patients were at risk for different syndromes—meaning that another test would have been more appropriate.

"This issue about BRCA1 and BRCA2 testing is of particular concern because genetic counselors are not recognized as healthcare providers," noted Brown. "As a consequence, this means physicians and nurses often serve as genetic counselors, despite their lack of appropriate training in this field.

WellPoint Launches Value-based Reimbursement, Wants Physicians to Utilize Lab Tests Appropriately

IN RESPONSE TO ONGOING HEALTHCARE REFORMS, WellPoint, Inc., one of the nation's largest private health insurers, is changing the way it contracts with its affiliated physicians, said Jill Hummel, WellPoint's Vice President of Payment Innovation.

"As is happening with most health plans, WellPoint is shifting away from fee-for-service reimbursement to value-based payment," Hummel said in an interview with THE DARK REPORT. "Under value-based payment models, WellPoint rewards providers when they improve quality while also reducing cost trends."

Wellpoint wants to engage laboratories to support these goals. "This year, WellPoint introduced physician-shared savings programs for physicians," noted Hummel. "When the medical costs for a defined population of patients is less than projected and physicians meet or exceed quality metrics, they can share in the savings.

"Physicians must meet a quality threshold to earn any savings," she said. "The better they perform on those quality metrics, the greater the percentage of savings they are entitled to share. In this way, quality benchmarks serve as both a gate and a ladder.

"Our goals are to reduce avoidable ER visits and hospital admissions by better managing patient health," Hummel explained. "We also want to reduce avoidable costs such as the cost of duplicate or unnecessary services. Laboratory testing is an important part of that equation.

"Whether it is ordering the right tests for the diagnosis, making price-sensitive referral decisions, or ensuring that patients follow through with ordered lab work, labs can play a big role in improving cost and quality.

"Wellpoint is asking its lab partners to help educate physicians about the tests they order for their patients and also help them ensure patient compliance," she said. "As physicians move to value-based payment arrangements, we want our lab partners competing for market share—not only on the basis of price—but also on the basis of the added-value services they offer to ordering physicians that will allow physicians to improve the health of their patients and thrive in this new payment environment.

"Doing so includes offering more consultative and other services, such as notifying the physician when a patient doesn't show up for a standing lab order, which will help the physicians to improve quality and reduce overall costs, not just lab costs," she added.

"We recognize that labs want to add market share and we believe our new physician payment models present an opportunity for our lab partners," concluded Hummel. "Labs in our network are learning that—under these new reimbursement models—the best way to grow market share is to offer market leading solutions that help physicians better manage the health of their patients while taking unnecessary costs out of the system. That's a win for our lab partners, for our physician partners, and, most importantly, for our members."

"The problem for labs is that they may be asked to provide tests that are inappropriate for certain patients and not all health plans will reimburse for inappropriate testing," she said. "Another problem for labs is that in general, insurers do not cover genetic screening tests. They cover only molecular and genetic tests when the patient shows symptoms of disease." TDR

—By Joseph Burns

Contact Trisha Brown at trishbrown@shamaconsulting.com; Linda Stewart at Linda_m_stewart@uhc.com; Brandon Davis at Brandon.Davis@Wellpoint.com.

CEO SUMMARY: When executives closed the doors of Pathwork Diagnostics last month, the simple explanation was that reimbursement for its proprietary molecular diagnostic test was inadequate. Indeed, that was part of the story. But other factors played significant roles in impeding growth at this lab company. Here is an inside look at six factors which contributed to the lab firm's closure.

Reimbursement just one of many issues at Pathwork Diagnostics

Why One Molecular Diagnostics Company Closed Its Doors

When Pathwork Diagnostics, Inc., ceased lab testing operations last month for its Tissue of Origin test, it was easy to conclude that a difficult reimbursement environment for molecular diagnostics was to blame.

Although technically not closed, the company has an agreement with creditors as of April 2. A message on its phone system told callers that it intends to resolve the issue within 30 days, according to a published report.

Indeed, inadequate revenue was a major cause for the lab company's closure. But the story at Pathwork Diagnostics, located in Redwood City, California, is more complex. It has useful insights for other labs performing molecular diagnostics assays and genetic tests.

The flagship product of the company was its Tissue of Origin test. This is a microarray-based molecular diagnostics assay for cancer patients with tumors of unknown origin and where the cause of the cancer is undetermined. The Pathwork Tissue of Origin test was FDA cleared and designed to help oncologists begin targeted therapies.

Pathwork Dx performed this test in its Redwood City laboratory. That lab was certified by CLIA and accredited by CAP.

The following interview is with Mark McDonough, who was Vice President of Sales and Service at Pathworks Dx from September 2008 through the mid-2012. He is currently President and CEO at **CombiMatrix Diagnostics** of Irvine, California.

"In my opinion, there are at least six significant factors the led to the closing of Pathwork Dx," McDonough said. "One factor was a decision to proactively pursue FDA clearance.

"With the benefit of hindsight, I would say that if it had to do it again, the company probably would not spend the time and money to obtain FDA clearance," McDonough said. "Getting clearance for the Tissue of Origin (TOO) test cost the company millions of dollars from 2006 through 2008. Our FDA clearance for our frozen TOO test was obtained in July 2008 and it cost the company a substantial amount of the Series A and B funding.

"That is a large amount of money which could have been used elsewhere in the development of our lab testing business to develop and expand our testing portfolio," he added. "Looking back, this is a difficult issue because leadership truly believed they were making a good calculation at the time.

"When I joined Pathwork, the assumption had been made that the reimbursement environment would get easier with FDA clearance," McDonough said. "That did not prove to be the case. Our experience was that the reimbursement issue was not any easier after getting the FDA clearance than before.

"In one respect, at that time, the Pathwork Dx Tissue of Origin test was somewhat ensnared by the FDA's declarations of its intent to regulate laboratory-developed tests (LDTs)," noted McDonough. "It is disappointing to think that any company would suffer as a result of proceeding in what it thought was the proper way to obtain regulatory clearance for its proprietary test, as Pathwork Dx did.

"But, at that time, it seemed that the largest lab companies with laboratory-developed tests didn't want the FDA to make a fast decision on regulating LDTs," he said. "Many great lab testing companies operate without FDA clearance. That is why some argue that FDA clearance is not currently a make-or-break factor with an LDT. That wasn't the position at Pathwork Dx. We were in favor of the FDA ruling that everyone had to use a FDA-cleared test and the FDA has yet to make such a ruling.

Just One Test On The Menu

"A second factor—the issue of having just one test performed by our laboratory—is related closely to the third factor of inadequate market size," he explained. "With just one test on the menu, it's clear—again in hindsight—that we needed to be diversified and serve a much larger market, such as that for colon, lung, or breast cancer.

"Those lab companies that have been financially successful with just one proprietary test have targeted colon, lung, or breast cancer—three markets that are quite

large," stated McDonough. "If Pathwork Diagnostics could have diversified by adding another diagnostic test—particularly one that helps identify colon, lung, or breast cancer—that would have proved immensely helpful to us. Having multiple products to offer is a necessary strategy in today's market environment and is more in line with my situation today at CombiMatrix."

McDonough also observed that the Pathwork Dx Tissue of Origin test was performed after the primary diagnosis of cancer had been made. This increased the difficulty persuading referring physicians to order this test.

"As it was, our physician clients had patients with metastatic disease and pathologists had already done their immunohistochemistry testing on those patients," he said. "To add our test at that point in patient care proved to be a difficult sell."

Inadequate Market Size

The third factor contributing to the demise of Pathwork Dx was that the size of the market was inadequate to support the company's business plan.

"In the early stages of our company's development, it was estimated that the market for our test was about 150,000 patients a year," continued McDonough. "After our sales force spent time speaking with the 8,000 oncologists who practice nationwide, we calculated that the number of cancers of unknown origin was much smaller.

"It was common for an oncologist to tell us that he or she would see about five to 10 cases each year involving a tumor of unknown origin," he recalled. "That is a market of 40,000 to 80,000 cases per year, about half of the original estimates of market size.

"Ultimately, we established that this was the realistic size of the market for cancers of unknown origin," McDonough commented. "That brings up the next reality about market size: The real market today is what your customers send you!

"We calculated that, based on the tests we ran and what we knew about the other leading competitor in this space, **Biotheranostics, Inc.,** that the real market was about 25,000 cases annually. This is the number of patients we could reasonably expect to be referred for a Tissue of Origin test.

Estimating Market Size

"Biotheranostics is a good company and they are the first mover in this area of testing for cancers of unknown origin," noted McDonough. "We estimate that, combined, the two companies were getting 7,000 to 8,000 tests per year.

"Further, we estimated that only about 30% of the patients who should get the test were actually getting the test," he said. "If 7,500 cases represent 30%, then perhaps the total estimated market—based on actual volume—is 25,000 tests per year."

This represents a sizeable gap between the more optimistic estimates of market size used by the test developers and venture capitalists when planning the launch of Pathwork Diagnostics, and the market realities identified after the sales force called upon oncologists and begin to generate case referrals.

This inaccurate and overly-optimistic estimate of the market size for testing of cancers of unknown origin encouraged the company's organizers and investors to move forward to launch its proprietary test. Further, at these lesser volumes of test referrals, that market niche would produce much less revenue than what the company needed to cover its cost to do business.

McDonough recognized this aspect of Pathwork Diagnostics' business strategy. "I don't dispute the estimate of 150,000 cases of cancer of unknown origin per year—which is what the market likely will be in 2016," he observed. "But when creating a market, every lab testing company must scrutinize what the market is today by data points that include what your physician customers say it is, along with

Pathwork Diagnostics: A Look at the Short Life and Times of the Lab and its Proprietary Test

LAUNCHING A PROPRIETARY MOLECULAR DIAGNOSTIC TEST OR GENETIC ASSAY into the clinical marketplace continues to be a high-risk business proposition. Last month's closure of Pathwork Diagnostics, Inc., of Redwood City, California, is the latest example of this market dynamic.

The company had a relatively short life of just seven years. It was 2006 when **Predicant Biosciences** acquired a company named **Pathwork Informatics** (itself formed in 2003) and changed its name to Pathwork Diagnostics.

The company was organized around a single proprietary test, the Pathwork Dx Tissue of Origin test. It was designed to help physicians treating patients with cancers of unknown origin. The microarray-based gene expression test used proprietary algorithms and measured the gene expression levels of 2,000 genes.

The test was designed to help doctors determine the type of cancer a patient has in these difficult-to-treat cases. In turn, this information would inform treatment decisions. Pathwork Dx's lab was CLIA certified and CAP accredited.

It is notable that Pathwork Dx twice obtained clearance for this test from the **Food and Drug Administration**. The first was in 2008 for use with frozen tissue samples. The second clearance was in 2010 for use with formalin-fixed, paraffin-embedded samples.

One published source says Pathwork Dx went through as much as $61 million in venture capital that was funded in three publicly-disclosed rounds. More capital may have been invested.

Medicare issued a positive coverage decision for the Tissue of Origin Test in 2011. In recent years, Pathwork Dx had conducted studies to demonstrate clinical validity and clinical utility. Some of these studies were published in the *Journal of Clinical Oncology* and the *Journal of Molecular Diagnostics*.

Adequate reimbursement for the Tissue of Origin Test was a constant struggle for the new lab test company. *PGx Reporter* published information from the federal Office of the Inspector General (OIG) on variability in payment rates among state Medicaid and federal employee health benefit programs (FEHBs) for several genetic tests, including the Tissue of Origin test. *PGx Reporter* wrote that the OIG's findings were that this test "was reimbursed at above $900 by Iowa's Medicaid program, but among FEHB plans the reimbursement varied from $5 to $38."

the actual test volumes that its customers submit to the lab."

The fourth factor was the type of specimen Pathwork Dx originally requested from the referring physician. "When we launched in summer 2008, our assay was only validated for testing on frozen tissue specimens," said McDonough. "During that time, several data points revealed that frozen specimens would never become a generally-accepted source of tissue specimens.

"In early 2009, we converted and began accepting formalin-fixed, paraffin-embedded (FFPE) specimens," continued McDonough. "Again, with the benefit of hindsight, if back in 2006, our company had decided to focus solely on FFPE, we would have given ourselves a much better chance for success and market share adoption. That late conversion was one factor that negatively affected our ability to build specimen volume to meet our goals."

The fifth factor was the rather late compilation of clinical utility data. "Having clinical utility data is essential in this reimbursement environment," he noted. "Obtaining reimbursement decisions from 2008 to 2011 was particularly difficult.

"Based on what we learned through hard experience, this is the time to have solid data on clinical utility," he added. "Payers want evidence on how use of the proprietary molecular diagnostic test contributes to improved patient outcomes. However, in our earliest years, gathering that data was not the same priority for us as gaining FDA clearance, for example.

"Thus, the company lost several years by not making an earlier investment in collecting that data," said McDonough. "We eventually had that data. But if we gathered it earlier, it could have made a bigger difference when we worked with payers to gain favorable coverage and reimbursement decisions."

McDonough was careful to distinguish between the two types of data that are typically associated with a diagnostic test. "The reason we didn't invest in clinical utility data was that we were convinced that our clinical validity data would carry the day," he explained.

Clinical Utility Data

"Clinical validity data shows how accurate our test was and that is important to physicians," he added. "But what is most important to payers is clinical utility data.

"In truth, doctors want both," he continued. "Therefore, when we told the doctors that we were 90% accurate, that was enough for them to trust the results produced by the Pathwork Dx Tissue of Origin Test. But some physicians—and all the payers—regularly asked a different question.

"That question was, 'how does this test affect a woman who is suspected of having ovarian cancer?' and it was asked when the physician was uncertain," he recalled. "They wanted to know if the test result would point them to a different treatment regimen that would improve outcomes by allowing the patient to live longer, for example."

This marketplace experience demonstrates how swiftly clinicians are moving toward the concept of companion diagnostics, where a laboratory test result is used specifically to guide the therapeutic decisions of the referring physician.

With the tidal wave of new proprietary lab tests washing over physicians in recent years, they are skeptical of any new molecular diagnostic test. McDonough saw that market phenomenom. "If physicians or payers are skeptical about the performance of your proprietary lab test, you have to address that skepticism and show that you're correct.

Clinical Utility Studies

"Pathwork Dx did those clinical utility studies two years too late," he stated. "In August 2012, at the time I left the company, we finally had the clinical utility study results, but by then we had burned through our capital resources and our window of opportunity to build market share was lost."

The sixth factor was variable reimbursement paid by government and private payers. From the launch of the Tissue of Origin test in 2006, adequate reimbursement was an ongoing challenge. "Rates were highly varied," McDonough stated. "Our average price per case 'all in' was $2,500 and the price from Medicare was about $3,100.

"But there were other payers who thought the test was good but still they would arbitrarily pay us just $1,300," he added. "Where there was no established code for our molecular test and others like it, payers paid whatever they wanted and our lab company had no recourse.

"It was late in the process when we obtained Medicare coverage at a very fair price," McDonough stated. "If that Medicare reimbursement had come one year earlier, it would have been a game changer for Pathwork Dx.

"As it was, we were still fighting to get coverage on nearly every claim from pri-

vate payers," he said. "Plus, we essentially counted every Medicaid payer as zero.

"Not only was this financially devastating to a young lab testing company like ours, but it is sad because this is a test that helps people," recalled McDonough. "We certainly don't want to preclude certain patients from critical testing because of their financial situation."

To be fair in his assessment of the closure of Pathwork Diagnostics, McDonough wanted to distinguish the impact from difficulties in obtaining favorable coverage and reimbursement decisions from government and private health programs compared with other business issues.

"I can't downplay the reimbursement challenges because it's a tough environment right now—particularly given how slow Medicare contractors are paying since the beginning of the year," commented McDonough. "But the molecular pathology issues that currently exist with the Medicare contractors are not the reason Pathwork Dx is closing.

"At the end of the day, the cost of sales and marketing was high, and the cost to run the lab was high," he noted. "When you look back, what happened to Pathwork Dx is sad. This test is something many of us were passionate about. But it's all about capital, and it's clear that we just couldn't invest enough in sales and marketing to get that critical mass of volume needed to break even."

A Test That Helps People

To conclude, McDonough said, "When I joined CombiMatrix, what was most appealing were the factors that were so different from Pathwork Dx: CombiMatrix offered a large portfolio of tests with a legitimately large market size opportunity of $600 million in the growing market of prenatal testing. The test portfolio helps parents and physicians make decisions and life preparations, and it is very rewarding." TDR

—Joseph Burns

Contact Mark McDonough at 949-226-9630 or mmcdonough@cmdiagnostics.com.

Lessons Learned in Launch of Proprietary Gene Test

BASED ON AN EXCLUSIVE INTERVIEW with the former Vice President of Sales and Business Development at Pathwork Diagnostics, Inc., six factors were discussed as having a role in the failure of the company to achieve its original goals for revenue, specimen volume, and market share with its proprietary Tissue of Origin test. In no order of priority or significance, they are:

1. At launch, the company pursued FDA clearance for its Tissue of Origin test but the clearance didn't increase sales as the company hoped. That led executives to question the wisdom of investing in such clearance at this early stage in the lab company's development.
2. The market size for cancers of unknown origin was estimated to be much bigger than what Pathwork Dx found as its sales force canvased the clinical marketplace. The original estimate of 150,000 cases per year was lowered to as few as 25,000 cases.
3. Pathworks Dx had only a single diagnostic test. It needed to provide a more diverse menu of molecular diagnostics assays to generate additional revenue and encourage more test referrals.
4. Use of formalin-fixed, paraffin-embedded tissue specimens should have been done at the launch of the test, along with frozen tissue specimens.
5. The company would have benefited by being faster at providing clinical utility data in direct response to the reimbursement questions from payers, thereby gaining more favorable coverage and reimbursement decisions earlier in the company's business life.
6. The reimbursement environment was challenging, particularly between 2008 and 2010. Reimbursement was highly variable and often inadequate to cover the cost of performing the test.

Managed Care Update

Aetna To Lower Lab Test Prices, New Fees Are Effective on July 1

Move is insurer's latest strategy to reduce what it spends on laboratory testing services

In recent months, labs are reporting the receipt of letters from **Aetna, Inc.**, announcing that it will pay dramatically less than Medicare prices for many key lab tests. Aetna said that these lower prices will take effect on July 1, 2013.

Three examples illustrate the deep fee cuts that Aetna is attempting to push onto laboratories providing medical tests for Aetna patients. In the clinical laboratory, Aetna says it will pay just $6.54 for CPT 80053-Comprehensive Metabolic Panel and $4.00 for CPT 85027-Complete CBC Automated. In the anatomic pathology laboratory, Aetna intends to pay only $35.05 for CPT 88305-Level IV Surgical Pathology, Gross and Microscopic.

Lower Lab Test Prices

Such cuts are causing concern at laboratories that provide testing to Aetna beneficiaries. Not only are most of the prices Aetna listed in its letter deeply-discounted below Medicare Part B clinical lab test fees, but these rock-bottom prices are significantly below a laboratory's fully-loaded cost of performing these tests.

For these reasons, Aetna may face stiff resistance in its latest attempt to slash what it pays labs for testing. Aetna has already shot itself in the foot with earlier attempts to exclude many local labs as network providers, consultants said. More on that failed strategy in a moment.

Labs must not view Aetna's pricing in isolation. If labs accept the Aetna pricing, other health insurers, such as **WellPoint**, **CIGNA**, **UnitedHealthcare**, and **Humana**, will want to follow Aetna's lead and ask labs for further price concessions.

Anatomic pathology laboratories can be expected to vigorously fight the lower fees announced by Aetna. "As of July 1, Aetna will pay $35.05 for an 88305," said Joe Plandowski, co-founder of **In-Office Pathology, LLC**, in Lake Forest, Illinois. "To put that in perspective, last year, CMS paid a national fee of $105 for 88305. But then, as of January 1, CMS cut that fee by a third, to roughly $70. And Aetna says it will now cut that fee even more, to $35.05, which is about 50% of Medicare's price.

"If Medicare and every other insurer starts paying only $35 for 88305, pathology labs will be unable to continue operating," he said. "They will be doing the 88305 test at a loss.

"Look at it this way: Last year, pathologists were getting $105 for the global fee for 88305," explained Plandowski. "Out of that global fee, pathologists got $35 for the professional component (PC) alone. But at $35 for the global fee, did Aetna completely forget about what pathologists do?

"Typically, the professional component represents about 35% of the global fee. But, in 2013, the PC for 88305 represents about 50%," he added. "Aetna's fee of $35.05 leaves just $17 for the pathologist.

"Moreover, the remaining $17 must cover lab costs: to pay the courier to deliver the specimen, to pay staff to prepare the tissue (the technical component), to pay overhead to operate the lab, and to

pay for sales and marketing as well," stated Plandowski. "At this price level, a pathologist would have to shut down the lab and close the doors."

In a letter sent to labs, Richard J. Gentleman, Aetna's Regional Network Operations Head, said Aetna was adjusting its standard fee schedule, called the Aetna National Contract Default, for all of its health plans. The fee schedule is based on the 2012 Resource-Based Relative Value Scale and CMS' Outpatient Prospective Payment System, Physician Fee Schedule, and Clinical Laboratory Fee Schedule. The letter lists prices Aetna will pay for some tests. *(See table in sidebar at right.)*

Aetna Provides A Statement

Aetna spokesman Ethan Slavin explained the company's position. "We have a national fee schedule for our nationally-contracted labs that takes into account the rates paid by Medicare, among other factors," he stated. "Aetna's national fee schedule has been below the Medicare rate for many years. Aetna has negotiated with many of our contracted labs for years. Aetna continuously monitors coding changes with Medicare/Medicaid fee schedule changes and we will adjust our national fee schedule as appropriate.

"Recently, CMS reduced rates on the Medicare fee schedule for surgical pathology fees so we made a corresponding adjustment to the base national fee schedule," continued Slavin. "On the network question: We routinely assess our network adequacy and costs by locale or region and adjust as necessary. Our job is to negotiate affordable rates for our members."

The story of Aetna's efforts to lower lab test costs starts a few years ago, when Wall Street financial analysts published research that identified Aetna as paying the most money for lab tests of any major health insurance company. Aetna's CEO, Mark Bertolini, reacted to this public disclosure by declaring that Aetna would move swiftly and aggressively to change this situation.

New Lab Test Fee Schedule Slashes Rates Aetna Will Pay

RATES SET TO GO INTO EFFECT on July 1, 2013, will be much lower than Aetna has paid in the past, according to consultants. Here is a sample of some of the new rates that were announced by Aetna:

80048	Metabolic panel total ca	$5.23
80050	General health panel	$22.65
80053	Comprehensive metabolic panel	$6.54
82306	Vitamin D 25 hydroxy	$18.32
85025	Complete CBC w/auto diff wbc	$4.81
85027	Complete CBC automated	$4.00
88185	Flow cytometry	$27.05
88304	Level III surgical pathology, gross and microscopic	$22.29
88305	Level IV surgical pathology, gross and microscopic	$35.05
88307	Level V surgical pathology, gross and microscopic	$148.68
88313	Special stains	$30.47
88342	Immunohistochemistry, each antibody	$57.67

What motivates this most recent move by Aetna to greatly reduce the prices it will pay labs for testing is its corporate goal to shrink the total dollars it spends on clinical laboratory testing and anatomic pathology services. That goal is itself a relevant story that will help lab professionals and pathologists understand why Aetna's actions seem to be a "declaration of war" against the medical laboratory testing profession.

Since 2007, Aetna has had an exclusive national contract with **Quest Diagnostics Incorporated**. Terms of this contract (and pricing discounts) meant that Aetna could not contract with **Laboratory Corporation of America** as one approach to lowering what it spends on lab tests.

That left Aetna with few options, so it apparently decided to pay all other labs much less money per test. Aetna's first idea was to boot hundreds of local lab out of its networks. Those exclusions took effect over the past 18 months.

One tactic Aetna used to exclude labs from its networks was to announce that it

would pay only those labs currently accredited by the **College of American Pathologists** (CAP). That turned out to be another poor management decision, since large numbers of respected laboratory organizations hold Medicare accreditation through other deeming authorities.

"One reason that Aetna issued its deep fee cuts to lab test pricing that take effect this summer is because of that earlier misstep with excluding labs from its provider networks since 2012," noted Plandowski. "Aetna had declared that, that by December 2012, it would pay only those labs that are accredited by the College of American Pathologists.

"CAP has accredited about 4,000 labs, and to meet Aetna's declaration, it would have to double that number," he continued. "Thus, Aetna put CAP into a bind, because CAP couldn't double the number of labs it accredits in less than a year.

"Aetna's next move was to declare that it would pay only labs accredited by CAP or **The Joint Commission**," he continued. "Aetna also moved the accreditation-required date forward to April, 2013, saying labs should be accredited or scheduled for accreditation."

Unpleasant Consequences

Even as Aetna was reacting to the issues caused by its attempt to make CAP accreditation a requirement before it would reimburse a lab's test claims, it found itself facing an unpleasant consequence from its tactic of excluding many local labs from its provider networks.

At the *Executive War College* in New Orleans earlier this month, attorneys and managed care experts discussed the problems that Aetna had created for itself. "Since January of this year, after terminating many labs that the insurer previously had considered to be in-network, Aetna got an unpleasant financial surprise," stated one lab industry consultant, who preferred to be unidentified for this story.

"Having terminated the provider contracts for many regional and local laboratories, these labs continued to provide testing for Aetna beneficiaries," explained the consultant. "All of these claims were submitted as 'out-of-network' claims and were thus reimbursed at a rate that was higher than the contracted rate Aetna formerly had with these same labs!

Strategy Backfires

"In this regard, Aetna's network strategy backfired," noted the consultant. "We believe that Aetna has seen a sharp increase in its out-of-network lab testing costs.

"Some may see this as poetic justice," the consultant concluded. "Aetna took a dictatorial approach. It chose to not engage local clinical laboratories to find common ground. Instead, it tried to cram its own solution down on them, in spite of years—even decades—of successful interaction with these same local laboratories. Now it reaps what it sowed."

There is more irony for Aetna in this situation. "Having booted many labs out of its network, Aetna now wants to entice labs to join its network at less than the rates that it currently pays Quest Diagnostics!" observed an attorney who represents pathology groups.

Plandowski had his own personal take on these developments. "The requirements instituted by Aetna will force labs to make the case about the value they offer," he said. "Meanwhile, the very low rates from Aetna (and possibly other private health insurers) will be a lingering problem for the entire lab industry.

"With all the price cuts labs face from Aetna and the Medicare program, it would not surprise me if a number of small labs close," mused Plandowski. "That will make the nation's largest lab companies happy because it will eliminate competition. But if we end up with only two labs operating in this country, then our healthcare system will have a problem." TDR

Contact Joe Plandowski at 800-280-3785 or iopath@bex.net.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Globalization of laboratory medicine continues to move forward. Two recent examples illustrate this trend. Earlier this month, the **University of Pittsburgh Medical Center** (UPMC) announced that it had entered into an agreement with the **Citizens Hospital** of Hyderabad, India, to form a clinical pathology laboratory in that city. The laboratory will be located on the hospital's campus and will operate under the name "**AmPath**." AmPath intends to earn local accreditation from the National Accreditation Board of Testing and Calibration Laboratories (NABL) and international accreditation from the **College of American Pathologists** (CAP). Separately, **PEPFAR** (U.S. President's Emergency Plan for AIDS Relief) has donated a new clinical laboratory facility to the **Ghana Armed Forces** in Takoradi, Ghana, Africa.

ADD TO: *Global Labs*

The new lab was built by the U.S. Department of Defense and is designed to support "military-specific HIV prevention, care and treatment programs, including HIV testing and counseling; diagnosis and treatment of sexually transmitted infections; and screening for tuberculosis in Ghana."

Pathologist to Edit Next Cancer Staging Manual

Editor-in-Chief of the upcoming eighth edition of the *AJCC Cancer Staging Manual* will be Mahul B. Amin, M.D., FCAP, who is Chairman, Department of Pathology & Laboratory Medicine at **Cedars-Sinai Medical Center** in Los Angeles, California. Traditionally, editorship of this manual is the domain of oncologists and surgeons. The appointment of Dr. Amin reflects the central position of pathology in the care of cancer, including use of molecular diagnostics and genetic testing in diagnosis, treatment, and patient monitoring for various cancers. Publication of the eighth edition of the manual is scheduled to be in 2015.

TRANSITIONS

- Deena M. Murphy joined **Pathology Associates Medical Laboratories, LLC**, as Senior Billing Director. She formerly worked for **Quest Diagnostics Incorporated**.

- Lewis Custer was appointed to the position of Senior Vice President, Operations, at **National Medical Billing Services**. Custer has held positions with Quest Diagnostics Incorporated and **United Healthcare's Mid Atlantic Medical Services, Inc.**, business division.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 17, 2013.

Join us in New Orleans!

Lab Quality Confab

and Process Improvement Institute

October 1-2, 2013

Astor Crowne Plaza Hotel • New Orleans, LA

Do you have a great story about using Lean, Six Sigma, and process improvement methods in your lab?

Let us know!

We are assembling topics and speakers for the upcoming Lab Quality Confab.

Contact us at:
rmichel@darkreport.com

For updates and program details, visit www.labqualityconfab.com

UPCOMING...

- ***Frustrated Labs Come Together to Create "Coalition to Strengthen the Future of Molecular Diagnostics."***
- ***Financial Planning for Balance of 2013 and into 2014: How Smart Labs are Exploiting Niche Opportunities.***
- ***New Ways to Reduce Lab Costs by Combining Lean Methods, Automation, and Middleware.***

For more information, visit:

www.darkreport.com

Sign Up for our FREE News Service!

Delivered directly to your desktop,
DARK Daily is news, analysis, and more.

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends