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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

New Federal Anti-kickback Investigation

POTENTIAL ANTI-KICKBACK VIOLATIONS in ancillary clinical service arrangements between referring physicians and providers like radiologists and laboratories continue to attract the interest of federal healthcare investigators. Right now, it appears radiology is a primary target.

Last week, the *Wall Street Journal* disclosed that federal health investigators issued warrants and subpoenas to **University MRI & Diagnostic Imaging Centers** of Boca Raton, Florida. The company, which operates three imaging centers, is owned by radiologist Fred Steinberg, M.D. This federal action comes in response to a whistleblower lawsuit against University MRI filed by a radiologist who once worked for the company.

At issue are allegations that University MRI entered into several different types of arrangements with referring physicians that violate federal anti-kickback statutes. In most scenarios, University MRI provided some type of discounted imaging service to the referring physician and allowed that physician to directly bill payers for the full amount. Federal investigators are looking for evidence that such arrangements represent kickbacks from the radiology provider to the referring physician.

It is widely-known that imaging is now the fastest-growing cost item for medical services in the Medicare program. The growth rate of imaging costs from 2003 to 2004 was 16%. Experts believe this is because so many physicians are bringing imaging services into their practice, then increasing utilization of such services.

Pathologists and lab directors should consider these developments in two ways. First, this investigation is targeting anti-kickback violations. Taken in context with the federal indictments of ex-**UroCor** executives under anti-kickback laws last year, it is reasonable to assume that the **Office of the Inspector General** (OIG) and federal attorneys are evolving and expanding their understanding and experience with this law. As that happens, more investigations and prosecutions of anti-kickback violations may occur in the coming years.

Second, to constrain utilization of imaging services, Medicare and private payers are likely to implement a variety of restrictions and requirements. There is a high probability that many of these types of constraints on utilization will be similarly applied to anatomic pathology services. TDR

For Quest and LabCorp, The Story is "Molecular"

Both lab companies racing to lock up most promising molecular technologies

CEO SUMMARY: Wall Street likes the potential of molecular diagnostics to infuse new revenues and operating profits into the laboratory industry. That is one reason Quest Diagnostics Incorporated and Laboratory Corporation of America are assertively seeking exclusive access to new molecular technologies. The latest such deal is Quest Diagnostics' $42.8 million agreement with Ciphergen Biosystems.

WAS IT COINCIDENCE that, on the same day that **Quest Diagnostics Incorporated** announced a molecular technology agreement with **Ciphergen Biosystems, Inc., Laboratory Corporation of America** issued a press release about its newest molecular diagnostics initiative?

The date was Friday, July 22, 2005. The day opened with a press release by Quest Diagnostics Incorporated that it had formed a "strategic alliance to develop and commercialize novel proteomic diagnostic tests based on Ciphergen's proprietary SELDI ProteinChip® technology."

By day's end on July 22, LabCorp had issued a press release titled "LabCorp® to Begin Validation and Evaluation of Roche Diagnostics' AmpliChip™ CYP450 Test." This AmpliChip test is the first microarray-based molecular assay to receive FDA approval for clinical use.

One notable difference in the two agreements is that Quest Diagnostics is making a major investment to access the Ciphergen proteomics technology. The three-year deal calls for Quest Diagnostics to pay $15 million to commercialize its choice of assays from Ciphergen's development pipeline.

Quest Diagnostics also purchased about 6.2 million shares of Ciphergen stock, worth approximately $12.8 million, along with a five-year warrant that allows it to purchase another 2.2 million shares of Ciphergen stock for $3.50 per share.

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Quest Diagnostics also agreed to loan Ciphergen up to $10 million "to fund certain development opportunities." This loan can be forgiven if Ciphergen achieves "certain milestones." Collectively, not counting the warrants, Quest Diagnostics is committing $42.8 million to access Ciphergen's proteomic technology.

Validation of AmpliChip

In the case of LabCorp and the Roche Amplichip, LabCorp's main statement was that it "announced today that it will begin validation testing of Roche Diagnostics' AmpliChip CYP-450 test." It further stated that it would assist Roche Diagnostics in evaluating its research leukemia microarray. This assay is intended to identify leukemia subclasses.

The fact that both lab companies released press releases on the same date indicates the importance of molecular diagnostics to their individual business strategies. The two blood brothers regularly tell the "molecular story" to Wall Street. Both lab companies believe that molecular assays will yield higher revenues and profit margins.

Molecular Technologies

Acquisitions and strategic alliances in molecular diagnostics testing remain one major growth strategy for each company. Both Quest Diagnostics Inc. and LabCorp America want to be first to lock up selected molecular testing technologies through exclusive agreements with strategic partners.

The molecular strategy was given prominent play in the second quarter earnings announcements by both companies. LabCorp had released its second quarter financial report on Thursday, July 21, the day before Quest Diagnostics publicized its deal with Ciphergen. Quest Diagnostics reported its second quarter earnings on Monday, July 25, 2005.

Both companies posted modest gains during the second quarter of 2005. Revenues at Quest Diagnostics Inc. climbed 6.2% to $1.4 billion. This was due to a gain of 5.3% in clinical testing volume and a 1.2% increase in revenue per requisition over second quarter 2004. Net income increased to $149 million, from $127 million for the prior-year period, a 10.6% increase.

At LabCorp, revenues totaled $853.3 million. This was an 8.8% gain over the same period in 2004. Specimen volumes grew by 1.1% and higher prices accounted for 7.7%. Net earnings were $106 million, compared to $98.3 million for second quarter 2004, an increase of 7.8%

Discussions With Investors

As these earnings statements show, both lab companies are experiencing about similar growth. However, there is an interesting difference in the business focus for Quest Diagnostics and LabCorp, as reflected in their public discussions with the investment community.

Based on these comments and company actions, it might be simply stated that Quest Diagnostics is emphasizing an "internal" strategy to drive up specimen volume, revenues and earnings. In contrast, LabCorp is more willing to pursue an "external" strategy to accomplish the same objectives. Certainly this comparison is relative, because each company is willing to bid or pursue any significant market opportunity that would generate more specimens and more revenue.

LabCorp's actions during the past 24 months reinforce its commitment to the external strategy—grow by acquiring another company's client-physicians. It was the winning bidder for the two biggest lab acquisition prizes of 2004-05, which were **US Labs, Inc.**

and **Esoterix, Inc.** Moreover, it continued to acquire small independent labs as well.

It should be noted that Quest Diagnostics was given the opportunity to place a bid for these acquisitions. The consistent outcome of LabCorp as the winning bidder suggests the relative importance of the external strategy to Laboratory Corporation of America versus Quest Diagnostics.

For its part, the language Quest Diagnostics uses with the investment community consistently emphasizes efficiencies and increased volumes—selling more to existing customers and winning new customers—and improving "customer satisfaction." Its executive team has stated that any acquisition or alliance prospect must be "patient grounded," reflecting a "patient first" perspective.

Six Sigma Quality Program

This is consistent with the major investment Quest Diagnostics has made in implementing Six Sigma quality systems throughout its network of regional laboratories. In public statements, the company has declared its intention to achieve a "new quality standard for the healthcare industry."

It must be emphasized that this corporate emphasis on internal versus external is relative. Certainly LabCorp has made plenty of statements to Wall Street about its efforts to improve operational efficiencies, boost quality and productivity, and increase customer satisfaction. And, every time LabCorp tenders a bid for a laboratory acquisition, Quest Diagnostics is considered a qualified and interested buyer for that same laboratory company.

Probably the most accurate conclusion is that Quest Diagnostics Incorporated and Laboratory Corporation of America are competing vigorously in every dimension of the laboratory marketplace. Any differences in style, strategy, or corporate philosophy stem mainly from the need by each company to publicly differentiate itself from its competitor.

After all, there are only a limited number of lab acquisition possibilities, or new diagnostic technology deals at any point in time. Short of capturing more market share from hospital laboratory outreach programs and the handful of remaining independent labs, acquisitions and exclusive access to new diagnostic assays are the most feasible way for either of the two blood brothers to generate increases in specimen volume and revenues. **TDR**

—By Pamela Scherer McLeod

One Molecular Deal That Never Panned Out

REMEMBER THE $75 MILLION DEAL between **EXACT Sciences Corporation** and Laboratory Corporation of America? It's a deal that shows the risks of paying for unproven molecular diagnostic technology.

Announced in June 2002, LabCorp began offering EXACT's PreGen-Plus™ for the early detection of colorectal cancer in the average-risk population in the summer of 2003. However, not enough physicians ordered the test.

Failure of the clinical market to accept this test was recognized by LabCorp in its second quarter earnings report. The company wrote off $3.1 million of its investment in the EXACT Sciences agreement.

This molecular technology agreement between a development company and a national laboratory is a reminder that every new lab test technology faces daunting hurdles to gain clinical acceptance and earn favorable coverage and reimbursement decisions from Medicare and major health insurers.

Lab Technology Update

Technology Can Now Enable "Card Swipe" for Draw Sites

First efforts to help physicians collect co-pays at time of service will also benefit laboratories

COLLECTING SMALL AMOUNTS of money from patients for deductible, co-pay, and self-pay fees has always bedeviled laboratories. However, new technology holds the promise of solving this long-standing problem.

BlueCross BlueShield of South Carolina (BCBC-SC) is currently offering a new "card-swipe" device to physicians in the state. The device lets insured beneficiaries see exactly how much their insurance plan will pay for medical services provided on that visit—while standing at the physician's reception station. This allows patients to pay, at the time of service, for the balance of the bill which will not be covered by their health insurance plan.

Collecting At Time of Service

THE DARK REPORT observes that this technology would be a great solution for laboratories throughout the country. At the time blood is drawn from the patient, such a card-swipe reader would allow the laboratory, in real time, to verify patient eligibility and provide a bill that shows the laboratory charges, the amount the health plan will reimburse, and the balance owed by the patient. This amount could then be collected before the patient leaves the phlebotomy draw site.

A simple fact is driving this development. More patients are now required to pay higher deductibles and co-pays, increasingly reaching more than $1,000. Since patients do not pay physicians with the same diligence they pay their credit card bills, health insurers now recognize they need to support physician efforts to collect this money.

"Real Time" Claims

BCBS-SC is not the only health insurer introducing "real time" eligibility and claims processing services for patients and physicians. **Humana Inc.** is testing a similar system in several regional markets where it has high concentrations of patients. The goal is to improve the ability of physicians to collect such money from patients while they are in the office.

Laboratory administrators and pathologists should track similiar initiatives by health insurers active in their local community. As the real-time eligibility and claims processing capability is deployed in physicians' offices, laboratories should be able to adapt this system to their own needs.

As an interesting side note, BCBS-SC intends to issue these cards to all its beneficiaries. The technology exists to add much more data to these cards, whether it is the patient health record or its use as a "debit card," allowing the patient to spend his/her HSA (Health Savings Account) balances during the course of the year. **TDR**

Pinkus DermPath Earns ISO-9000 Certification

Inspired by early-adopter laboratories, pathology lab implements quality system

CEO SUMMARY: After learning about quality management systems at a recent* Executive War College*, the lab director at Pinkus Dermatopathology recognized how such techniques could be used in his lab to improve quality, reduce errors, and create a better working environment for both pathologists and lab staff. ISO-9000 was the quality system of choice because of its wide use by businesses throughout Greater Detroit.

MOTIVATED TO CONTINUALLY improve their work proceses in the laboratory, **Pinkus Dermatopathology Laboratory, PC**, of Monroe, Michigan recently passed its audit and was certified as ISO-9001:2000 compliant.

Pathologists and laboratory administrators will find this story interesting for at least three reasons. One, it demonstrates the importance of continual access to cutting-edge ideas on laboratory management. Two, it is a useful case study on the benefits of quality management systems in laboratory operations. Three, it connects the strategic decision to implement a quality improvement program to the bigger picture of the revolutionary changes already set in motion by the consumer-driven healthcare trend.

"We were quite interested in improving the processes at our lab," recalled Darius Mehregan, M.D., Laboratory Director at Pinkus. "We recognized that too many resources were devoted to responding to problems regularly generated by our existing work processes," he said. "We wanted a solution that would permanently eliminate those problems and allow us to redirect those resources to higher-value purposes.

"In 2003, while attending the *Executive War College*, I learned of innovative lab management techniques that I had not been aware of before," said Mehregan. "These techniques could have a powerful impact in our dermatopathology laboratory. Implementing a quality improvement system in our lab was a strategy to improve work processes and raise the quality of our services."

Looking For Expertise

Having made the decision to "go quality," Pinkus faced two specific challenges. First, it needed to select a specific quality improvement program. Next, it wanted to find an experienced consultant to help it implement its quality project.

"When I returned to Monroe after the *War College*, I noticed how most large employers in the Detroit area were

ISO-certified," stated Mehregan. "We looked into Lean and Six Sigma, as well, but ultimately chose ISO-9000. We knew this quality system was recognized and understood by consumers in Detroit. After all, many Detroit-area residents are employed in auto industry companies with ISO-9000 certification. Pinkus Dermatopathology wanted to take advantage of that existing "brand recognition" among our patients and client-physicians.

The Pinkus laboratory was originally founded in the 1940s by Hermann Pinkus, M.D. and serves southeastern Michigan and northern Ohio. It handles an annual volume of 75,000 cases and has reference clients throughout the United States.

Attacking Common Issues

"Our staff consists of four dermatopathologists and 35 full-time and part-time technical and support staff, including about ten lab techs," stated Mehregan. "We faced the usual administrative problems common to most laboratories. Nothing really major—just a daily flow of little time-consuming problems that gnaw away at productivity—and profits."

Pinkus decided to implement the ISO-9001:2000 quality system. It next faced the challenge of finding the right consultant. "Because so few providers have implemented some type of quality system, it is not easy to find an ISO-9000 consultant with experience in healthcare applications, much less laboratories," noted Mehregan. "We finally chose a consultant based on her familiarity with the Healthcare ISO Guidelines and compatibility with our laboratory personnel."

"The first step in the consulting process took three or four days," explained Mehregan. "The consultant asked questions and observed work processes in the laboratory. "The consultant worked primarily with our laboratory supervisor. She observed laboratory tests from intake to manufacturing of the slides, supply ordering, and sending results to the physicians.

Analysis of Work Flow

"The consultant also observed our pathologists—how they read slides, what they did with the slides, how they made their reports, and how they handled phone calls. She observed the processes in our reporting and billing departments, as well as those of the business manager," he added.

"Following this observation period, we met with the consultant to review her recommendations and time lines," Mehregan said. "We committed the next several months to learning and implementing the ISO techniques. Each department had a list of goals to accomplish by a specified date.

"The first task of each department was to provide more information on its processes," he noted. "Throughout the remainder of the sequence, we had a full-day meeting with the consultant every two to three weeks. This time was spent reviewing our progress and establishing new goals. The entire assessment, training and implementation took about six months.

Used Existing Staff

"ISO certification did put additional demands on our workforce," stated Mehregan, "but not unreasonably so. We achieved ISO certification with our existing staff, and without utilizing any temporary help. Much of the quality improvement process consists of identifying procedures, writing them down, and revising work practices to conform to quality standards.

"The bulk of this work, revising our administrative procedures, was handled by our general administrator," he noted. "Our head technician reformatted the technical portion of our

manual and did the editing, with my assistance. To help produce the manuals which resulted from this work, we temporarily drafted an assistant from our reporting department.

"There was varied reaction by our staff to this quality improvement initiative. Some of our senior employees were more resistant to the changes. Others were very proactive and enthusiastic. For example, one-half of our employees volunteered to show up on a Saturday for training on how to conduct mock inspections," said Mehregan.

"It took us about five months to begin fully 'living' the ISO standards in our daily work habits," Mehregan continued. "We spent an additional 12 weeks practicing the techniques in preparation for the final stage—the inspection process. The biggest milestone occurred when our employees, assisted by the consultant, conducted a mock inspection in anticipation of the real inspection by the ISO certifying organization.

Easier Accreditation

"The drill served us well. Our consultant proved to be much more demanding than the actual inspectors, so we passed our certification easily," he recalled. "We found the ISO inspection to be similar to a JCAHO inspection. Fortunately, we had integrated all the CAP and JCAHO requirements into our ISO standards. That has made this year's inspections by CAP and JCAHO a relatively simple and easy process. This was an unexpected benefit of the ISO-9001:2000 certification program.

"Our strategic decision to adopt a quality improvement system meant a number of changes in our laboratory," reflected Mehregan. "While we did not make any changes to our equipment, we did have to change a couple of our stain and chemical vendors. That is because ISO certification requires that all vendors be ISO-certified.

"There were no changes in workforce. The main change in our workflow process involves how we deal with non-conforming specimens—such as bottles sent in without sheets, sheets sent in without bottles, and bottles sent in empty," he explained. "Prior to ISO standards, each non-conforming case was handled ad hoc by the chief technician, who would alert the physician. Now there is a documented procedure to follow for this event. It works more smoothly, takes less time, and is less frustrating for physicians, staff, and clients."

"Because our work processes now perform at a higher level of efficiency and quality, we have significantly fewer client complaints."

"While it will take at least 24 months to recoup the $30,000 to $40,000 we spent to become ISO-certified, the real benefit is the increased efficiency in our operational processes," stated Mehregan. "Because our work processes now perform at a higher level of efficiency and quality, we have significantly fewer client complaints. All of this translates into a happier workforce, a more stable customer base, and greater growth for our laboratory."

The benefits which resulted from the ISO-9000 certification of Pinkus Dermatopathology Laboratory show how pathology laboratories can benefit from introduction of a quality management system. By taking this step, Pinkus joins the growing number of labs which have "gone quality" in their management systems. TDR

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—by Pamela Scherer McLeod

Gauging Clinical Effectiveness Against Costs

Molecular Diagnostics: How Beaumont Built A Successful Program

CEO SUMMARY: It was about 15 years ago when William Beaumont Hospital and Beaumont Reference Laboratories first began offering molecular diagnostic testing services to clinicians. This successful effort came about because of effective strategic planning, use of consulting expertise at key junctures, and careful evaluation of the finances for each molecular assay added to the menu. Here's a step-by-step assessment of how this laboratory's executive team built their molecular program. Learn why hospital administrators supported this program and provided the needed funding.

IT'S A TOUGH ENVIRONMENT for most community hospitals to establish a financially-sustainable molecular diagnostics program. That is why the sustained growth in molecular testing at **Beaumont Reference Laboratory** (BRL) teaches some useful lessons.

"The molecular market is untapped," stated Frederick L. Kiechle, M.D., Ph.D. "There's a lot of money out there," Kiechle serves as Chairman of the Department of Clinical Pathology at **William Beaumont Hospital**, and as Medical Director of Beaumont Reference Laboratory, its for-profit outreach lab. Kiechle launched the molecular laboratory at WBH in 1991, three years after assuming his leadership role.

"Laboratories interested in pursuing a molecular program will face three initial challenges," observed Kiechle in a presentation at the *Executive War College on Lab and Pathology Management*, held in New Orleans last May. "The first challenge is to identify opportunities. The second is the actual development of the molecular dimension in your lab. Third is the knowledge needed to do the first two. Creating and managing a molecular testing program draws upon a different base of knowledge and management planning skills."

Beaumont is a two-hospital health system. Its flagship is **William Beaumont Hospital** in Royal Oak, a tertiary care hospital which handled 6.5 million procedures in 2004. At 1,061 beds, it is among the largest inpatient hospitals in the country. **Beaumont Troy Hospital** is a 254-bed community and teaching hospital and is ranked among the nation's busiest smaller community hospitals.

To develop an effective molecular diagnostics strategy for Beaumont, Kiechle's team did their homework. "From the beginning, we had four key objectives which we viewed as benchmarks for a successful molecular program," Kiechle said. "First, we needed to support the yearly specimen volume growth rate of 10% to 20% at BRL. Second, we wanted to generate revenue cycle metrics to monitor financial data for BRL and the hospital. Third, we immediately wanted to address the need for adequate capital equipment funds for future needs. Fourth, we knew we needed to reduce the number of send-out tests."

1 KEY OBJECTIVE ONE: Support Outreach Lab's 10%-20% Annual Growth Rate

"WE KNEW OUTREACH GROWTH at BRL would help our molecular program, just as the availability of molecular testing would help BRL's continued growth," noted Kiechle. "Growth of both programs has been mutually interdependent. Both lab operations benefit from increases in the numbers of clients and test volumes.

"Essentially, the business strategies for growth in molecular testing and outreach specimen volume at BRL were developed in tandem over the past decade," he continued. "This supported expansion in our molecular test menu and one measure of success is this statistic: the molecular lab grew 13% in 2004, from 38,792 procedures in 2003 to 43,824 procedures last year.

2 KEY OBJECTIVE TWO: Generate Metrics to Measure Revenue Growth Cycle

"PRECISE MANAGEMENT requires timely, detailed, and accurate data," noted Kiechle. "From day one, we organized our program so as to provide us with rigorously-measured financial data. We then used this information to drive management decisions about everything from test selection to technology, equipment, space, and staffing needs.

"For example, William Beaumont Hospital hired a consulting company called **Healthworks Alliance, Inc.** to

Beaumont-Royal Oak: Dept. of Clinical Path Timeline & Molecular Lab Development

- **1988** Kiechle becomes Chairman of William Beaumont Hospital Pathology Department
- **1989** Started POCT
- **1991** Started the molecular lab
  - First annual DNA Symposium
- **1993** Beaumont Reference Lab is launched
  - Clinical toxicology first offered
  - Signed PCR license agreement with Roche
- **1996** Started analytical cytology
  - Introduced NG/CT by Ligand Chain Reaction
  - Lab turns profitable
- **1998** Bought first Sysmex HST line/Sysmex Coagulation line
- **2001** Lab moves into new building
  - Introduced Roche Modular System, preanalytical and analytical chemistry line.
- **2004** Updated to Sysmex HST-II line
  - Introduced Lipoprotein (a)
  - Becomes a Roche "Molecular Center of Excellence"
- **2005** Introduced second Roche modular automation line
- **2005** Introduced immunochemistry line from Bayer

review the hospitals' revenue "pipeline"—more specifically, what we referred to as our 'leaky pipe'," observed Kiechle. "The problems identified are familiar to all hospitals and laboratories. Revenue leaks could be attributed to: no referrals, registration errors, insurance not verified, no authorization, chargemaster incomplete, and out-of-date CPT coding.

"With the help of HealthWorks, WBH assembled five different employee teams to analyze these problems and implement fixes," Kiechle noted. "The teams targeted five specific areas: comprehensive contract management, dedicated authorization, chargemaster maintenance, real-time code scrubbing, and comprehensive denials management.

"Also, each department formed a revenue cycle team to investigate contracts and develop metrics for that department, which, in our lab, we now review on a monthly basis," Kiechle explained. "One issue stood out above the others. It was apparent that we needed comprehensive contract management.

3 KEY OBJECTIVE THREE: Secure Funding for Future Equipment Needs

"CONVINCED BY OUR DETAILED STUDY of the market and our well-developed business plan, supported with detailed benchmarks and measurements, our administration made a commitment to fund the molecular laboratory's start-up and initial growth," stated Kiechle. "This included our request for capital equipment funds. Further, administration understood that it would take at least three years to achieve profitability."

4 KEY OBJECTIVE FOUR: Reduce the Number of Send-out Tests

"AS A RESULT OF OUR METRICS STRATEGY, we determined which tests we could bring in-house, and when," said Kiechle. "Further, our comprehensive contract management initiative contributed to this effort. That team, after its review of BRL's send-out testing, was able to reduce that number by 31% in one year. This strategy alone generated annual savings of $548,000!"

With these four key strategies as a guide, implementation of the clinical molecular testing program at Beaumont was organized around six target areas. "For example, our first concern was to accurately determine our market share potential, in terms of: 1) geographic area; 2) population; and, 3) physician mix," stated Kiechle.

"Next, we used this information to determine our molecular test menu. The third, fourth, and fifth target areas involved assessment of our technology, our work force skills, and physical space needs. Sixth, we had to create an effective marketing strategy for our molecular services," he explained.

MANAGEMENT TACTIC ONE:

Know Market Share Potential for Molecular Testing Services

"OBVIOUSLY IT IS IMPORTANT TO KNOW the mix of specialty physicians and how they utilize molecular tests in your lab's service area," commented Kiechle. "We started this process by tracking reference lab client utilization. We wanted to determine which subspecialties were ordering which procedures, and how many they ordered.

"We looked at the number of physicians who actually ordered molecular assays," he continued. "We wanted to identify how many procedures per physician were ordered in each group practice. This allowed us to zero in on the specialties of internal medicine and ob-gyn as the physicians most likely to regularly order molecular tests.

"The next dimension of our marketing study was to identify the number of physicians in these specialties and estimate the potential annual volume of molecular tests they are likely to order each year," added Kiechle. "This marketing estimate was confirmed by doing a population study for our laboratory's service area.

"Here is where **Roche Diagnostics**, and their 'Molecular Center of Excellence' program provided us with experience and expertise," noted Kiechle. "With their help, we determined the range of geography around Greater Detroit that could be in the BRL service area. This became our target market.

"Next, we calculated the population within our target market," he said. "Using the national numbers for molecular diagnostic revenues, we determined what percentage of that national sales figure would be generated by the population in our market against the national population. In our case, that yielded a potential market for us of $43 million for molecular diagnostics testing."

"We considered a potential molecular market of $43 million to be worth pursuing. This is the economic justification of our business plan and shows the health system administration that we know our business," Kiechle stated.

"The next step in our marketing study was to determine the specific types of tests and the volume of test orders that will originate from client physicians in our target market," he noted. "We started by looking at our two hospitals that do testing, Beaumont Hospital at Royal Oak (which includes BRL), and Beaumont Hospital at Troy.

"This uncovered valuable insights. For instance, we discovered that Factor V Leiden was more popular in the inpatient/outpatient arena at WHB in Royal Oak than it was in the inpatient/outpatient arena of the Troy facility or the outreach arena of Beaumont Reference Lab.

"The study also revealed that HPV is extremely popular in the outreach segment of our laboratory business," Kiechle said. "The lesson to pass along is that it is important to study the target population of referring physicians to identify their ordering patterns before setting up molecular tests."

MANAGEMENT TACTIC TWO:

Selecting the Right Molecular Tests to Offer

"OUR FIRST CRITERION for selecting our test menu was determining which send out tests we could convert to in-house," he observed. "Second, we studied send-outs from a profit perspective—that is, looking not just at the volume of tests we sent out, but the charges paid to the send-out lab.

"These charges are rarely recovered by billing the patient's insurance, due to a Michigan law which does not allow referring laboratories to mark up tests over the cost paid to the send-out lab," explained Kiechle. "For the tests we bring in-house, we estimate revenue based on our cost to perform the test compared to average third-party reimbursement for that test.

"In 1992, we started with three Southern Blot assays," Kiechle stated. "We expanded our test menu considerably when we introduced **Tm Bioscience's** extended panel for inherited disorders.

"Currently we perform about 30 molecular tests. We will soon introduce the 9-test Ashkenazi panel and an extended inherited thrombophilia panel," he explained. "We are also expanding our microbiology/viral assays with tests for *Herpes simplex I and II* (HSV), *Enterovirus*, and *Varicella-zoster* virus. That will increase our molecular test menu to about 40 assays. We plan to introduce a new molecular assay about every three months.

"To sustain our profitability, we monitor, on an ongoing basis, which tests are making money and which are not," noted Kiechle. "Every molecular lab needs to assess its money-makers against its money-losers.

"Molecular labs have an ongoing problem getting paid for some tests. They may have contracts with major health insurers with reimbursement that covers only a fraction of the actual cost of performing certain molecular assays," said Kiechle. "For that reason, it is prudent to know exactly what major payers will reimburse for a molecular assay before your laboratory makes the decision to set up and offer that test to clinicians."

MANAGEMENT TACTIC THREE:

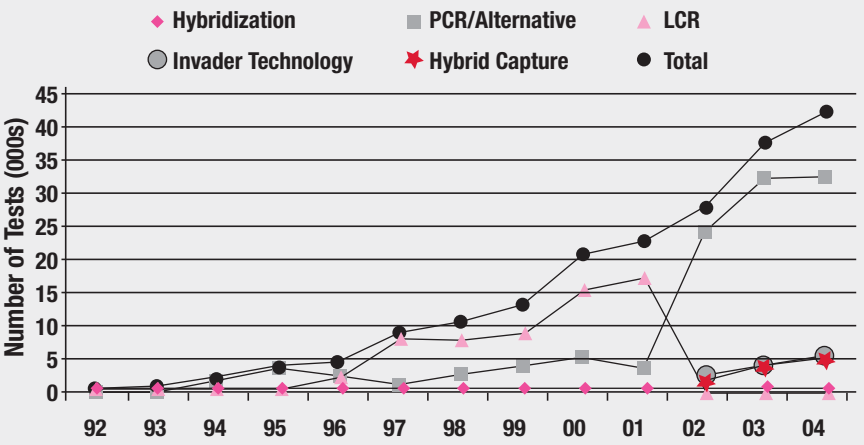
Develop an Effective Marketing Plan

"IT'S NOT ENOUGH to have the best clinical molecular testing program in your area if physicians remain unaware of it and how they would benefit," stated Kiechle. "That is why it is essential to develop a good marketing plan and support the molecular testing with a focused sales campaign.

"Our marketing study told us what molecular tests were wanted by physicians in our service area. We also knew which specialties would utilize these tests regularly," he explained.

"So the next step was to develop a marketing strategy and get sales reps into the field to let physicians know that they could order these molecular assays from BRL and to educate the clinicians about when to order such tests and how to follow-up the results," continued Kiechle. "The investment in a sales staff is significant, but the results are worth that investment. We also received a lot of

WBH/BRL Molecular Pathology Laboratory Test Volumes



This chart shows the steady growth in test volumes for the molecular diagnostics program at WBH/BRL. In particular, note how the total number of molecular tests performed annually has increased in each of the past 12 years.

valuable assistance in this effort from Roche Diagnostics' 'Molecular Center of Excellence' program. We didn't want to go out and reinvent the wheel by ourselves. We wanted our marketing and sales campaigns to succeed from day one.

"Our first marketing step was to produce a brochure that listed all the molecular tests we offered at that time," stated Kiechle. "Next, we developed individual marketing pieces for each molecular assay. These described, in detail, what the assay could do, how to use it clinically, how to interpret the positive and negative, and what value it would add to patient care.

"Now that we've been in the market for several years, we regularly survey test ordering patterns of our physician-clients," he added. "In offices where we think they are not using tests to the maximum benefit of their practice, we use these single pieces, along with test samples, to educate them about the value of such tests."

Another key aspect of our early marketing campaign was what we called our "DNA Symposium." The symposium provides an elementary introduction to molecular diagnostics. It attracts laboratorians from the four or five states surrounding Michigan, as well as foreign visitors from as far away as Europe and South America," commented Kiechle. "It has increased the credibility of our molecular diagnostics program within the clinical community."

According to Kiechle, the clinical molecular diagnostics program at BRL has attained six noteworthy achievements. "First, we converted our high-spend molecular send-out tests to in-house procedures," he noted. "Second, we aligned test

Top Ten Molecular Test Opportunities In WBH/BRL's Local Marketplace

NO.	MOLECULAR TEST NAME	Reportable Test Volumes U.S. MARKET	TOTAL NO. OF TESTS DETROIT METRO 1.41%	WBH CURRENT	% SHARE OF DET-METRO
1	CHLAMYDIA / N. GONORRHEA	30,000,000	423,000	34,544	8.2%
2	GROUP A STREP (GAS)*	8,000,000	112,800		
3	GROUP B STREP (GBS)*	3,000,000	42,300		
4	HIV QUANTITATIVE	2,700,000	38,070	1,596	4.2%
5	CYSTIC FIBROSIS (CF)	2,000,000	28,200	1,822	6.5%
6	HUMAN PAPILLOMA VIRUS (HPV)	1,500,000	21,150	2,930	13.9%
7	HEPATITIS C VIRUS QUANTITATIVE (HCV)	1,100,000	15,510	1,130	7.3%
8	HERPES SIMPLEX 1&2 (HSV)	600,000	8,460	88	1.0%
9	FACTOR V	280,000	3,948	1,582	40.1%
10	CYTOMEGALOVIRUS (CMV)	250,000	3,525	192	5.4%

Here is one analysis derived from WBH/BRL's study of the market potential for molecular diagnostics in its market service area. In this analysis, the national ratio of molecular tests performed per 100,000 population was determined for each molecular assay. This ratio was then applied to the population of the regions served by the WBH/BRL laboratory, resulting in an expected demand for that test. This number was then compared to actual tests performed to determine the market share currently held by WBH/BRL. This allows the sales/marketing team to concentrate its efforts where the return will be greatest.

charges, costs, and reimbursement to attain a positive margin. Third, we effectively evaluated the specific needs of our market, then filled that need with our enhanced molecular test menu.

"Fourth, our marketing campaign generated sustained growth in our client base—for more than fifteen years," Kiechle said. "Fifth, we did a good job educating our targeted client segments in molecular testing and utilization. Knowledgeable clinicians are one reason why molecular test volumes grew in such a sustained manner. Sixth, we effectively monitored our clients' ordering patterns to determine ordering patterns by specialty and to identify opportunities for up-selling."

MANAGEMENT TACTIC FOUR:
Assure a Qualified Workforce

"A GROWING MENU of molecular tests requires a growing workforce of individuals trained in these technologies," he said. "At the launch of our clinical molecular testing program, we hired an M.D., a Ph.D., and several medical technologists. Our molecular lab now has a medical director, one Ph.D. technical director, and seven M.T.s.

"We have an interesting M.T. internship program," Kiechle stated. "We give our interns loans, instead of stipends. If they work for Beaumont

for a certain period of time, the loan is forgiven. They have an incentive to stay.

"In 1991 we started our 'DNA Symposium'," he continued. "It provides an elementary introduction to molecular diagnostics, with pragmatic training in molecular laboratory testing, processes and operations. It is designed to appeal to all levels of medical personnel interested in molecular diagnostics, from physicians to technicians.

"As I mentioned earlier, this program is very practical and explains how to make molecular technology work in your lab. This symposium has accomplished two things. It has added to the credibility of our molecular testing program and has helped us identify individuals interested in working in our molecular lab."

MANAGEMENT TACTIC FIVE:

Anticipate Technology Benchmarks

EVERY MOLECULAR DIAGNOSTICS program needs a strategy for introducing and updating technology to coincide with expansion of its test menu and volume," noted Kiechle. "This is the payoff to your original objective of securing adequate capital equipment funds for future needs.

"At start-up in 1992, our capital outlay for equipment was $200,000. At that time we were performing three molecular assays and did a total volume of 307 that year," recalled Kiechle. "In 1993 we obtained our PCR license and the equipment required to do this type of testing. This helped immensely in our ability to introduce that technology and use it to expand specimen volume and revenues.

"We've followed a parallel strategy in our clinical laboratory. Funding to acquire new instrument systems and laboratory automation solutions has allowed us to keep pace with growth in specimen volumes—while generating the revenues necessary to amortize our capital investments and return operating margins back to the lab and our health system," observed Kiechle.

MANAGEMENT TACTIC SIX:

Secure Appropriate Space

"A MOLECULAR testing program not only needs appropriate equipment and qualified people to do the work," stated Kiechle, "but also must have an appropriate setting. Our laboratory occupies three and a half floors in what's called the Research Institute. It is a building designed to properly support clean rooms and other facility features necessary for molecular testing. It is also designed to support workflow for other laboratory processes. The building has easy access for our reference lab couriers, for example. It allows us to support inpatient, outpatient, and outreach testing activities from this centralized site."

Improvement Goals

To further build upon these achievements, Kiechle can identify several improvement goals for the BRL molecular testing program. "We want to improve our revenue cycle data," he stated. "Success ultimately hinges on our ability to make decisions based on hard facts—read 'accurate, detailed, and timely data.' We want to carefully look at a full year's revenue cycle in our department to see how well we've performed. That means doing a complete payment validation of every transaction that has taken place.

"As part of this revenue cycle study, we intend to define all the discrepancies between contract charge and actual payment. This is a definite problem on the molecular side. For

now we use the test costs that we know, along with average reimbursement figures for those tests. These numbers go into our financial models. We've engaged some consulting resources to help us in this effort," commented Kiechle.

"Patents, licensing fees, and royalties are also an issue that calls for a united response from the diagnostic testing community," declared Kiechle. "The negative impact of gene patents is substantial and frequently discourages the utilization and development of genetic tests."

"Another initiative we've launched is to do a better job of educating third-party payers about the value provided by molecular-based diagnostics," he explained. "All of us in the laboratory industry need to become more proactive on this point. We must consistently emphasize and inform payers about the value of the tests we provide.

"Next comes the issue of licenses and royalties," he continued. "In a not-for-profit health system, these types of costs can be budget-busters. We'd like to find innovative and legal ways to work around patents and licenses. One strategy is to use ASRs (analyte-specific reagents) as a source of new assay protocols.

"Patents, licensing fees, and royalties are also an issue that calls for a united response from the diagnostic testing community," declared Kiechle. "The negative impact of gene patents is substantial and frequently discourages the utilization and development of genetic tests. This is not good for the laboratory business nor for patient care."

For Beaumont Reference Labs, the success of its clinical molecular diagnostics program is no accident. From its inception, the executive team at BRL has taken the time to carefully study the proposed services, gather accurate data, and then develop a detailed business plan. This is good management execution and maximizes the ability of the lab to succeed with the proposed business plan.

Armed with good numbers and a good plan, and supported by the expertise from several of its key laboratory vendors, BRL's lab leaders gained the confidence of the parent health system administration. Pathologists and lab directors interested in expanding their own molecular testing activities should take careful note of this fact.

BRL's lab administration made a solid business case to their bosses. After gaining the go-ahead, the lab maintained its credibility with the parent health system by achieving the financial and performance objectives defined in the business plan. This creates a collaborative environment between the laboratory and health system administration.

Molecular Test "Winners"

Seen from these perspectives, the story of BRL's flourishing molecular testing program is one of good management execution. In its next installment about the WBH/BRL molecular testing program, THE DARK REPORT will look at how this laboratory identifies molecular "winners" and molecular "losers" on its testing menu. TDR

Contact Frederick L. Kiechle at 248-551-8030.

—By Pamela Scherer McLeod

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Redwood City, California-based **Genomic Health, Inc.** is considering an initial public offering (IPO) to raise as much as $75 million. The company filed preliminary documents with the **Securities and Exchange Commission** (SEC) on July 15, 2005. In January 2004, Genomic Health launched Onco*Type* D™ for early-stage breast cancer patients. The company is assembling clinical data to provide evidence that its test has the "ability to predict the likelihood of cancer recurrence, the likelihood of patient survival within 10 years of diagnosis, and the likelihood of chemotherapy benefit."

SPECIALTY LABS GETS WEAVIL AS CEO

On July 25, 2005, **Specialty Laboratories Inc.** stated that David C. Weavil had joined the company as Chief Executive Officer. Weavil was CEO of **Unilab Corporation** from 1997-99 and had previously been the Executive VP and COO of **Laboratory Corporation of America.**

HOSPITAL REPORTING OF MD DISCIPLINARY ACTIONS IS CRITICIZED

Patient safety advocates are opening a new front in the battle to develop transparency in the performance of physicians. Now coming under scrutiny is under-reporting of hospital-based disciplinary actions against physicians. The **National Practitioner Databank** was created in 1990 to collect this data. In 15 years of operation, the databank has collected an average of 720 reports per year from among the nation's 4,900 acute-care hospitals. Experts originally predicted that as many as 10,000 reports per year would be submitted.

ADD TO: *Disciplinary Action*

In a report on this situation released in 1995, the Inspector General of the **Department of Health and Human Services** (HHS) criticized the hospital industry for under-reporting and noted that its investigators had determined that 76% of the nation's hospitals had never reported a single disciplinary action in the first three years of the program's operation. Heightened scrutiny of the National Practioner Databank at this time is another step to peel away the veil of secrecy that keeps the public from learning about the poor clinical performance of some physicians. Advocates of reforming the American healthcare system want the names and details about physician disciplinary actions and license suspensions to be readily available, to both healthcare policymakers and consumers.

PAYER PROFITS UP

At this stage in the health insurance financial cycle, major health insurers continue to report strong earnings. **Aetna, Inc.** reported that second-quarter net income was $1.35 per share, a 50% percent increase over the prior-year quarter. At **PacifiCare Health Systems, Inc.**, soon to be acquired by **UnitedHealth Group**, second quarter earnings per share was $0.96, a 20% increase from same quarter 2004. **WellPoint, Inc.**, (formerly **Anthem, Inc.**) the nation's largest health insurer, saw its net income jump 135%, from $237.9 million to $559.4 million

That's all the insider intelligence for this report.
Look for the next briefing on Monday, August 22, 2005.

UPCOMING...

- ***Molecular Diagnostics Market Grows: Surprising List of "Top Ten" Vendors.***
- ***Shrewd Application of Lab Automation and Lean Methods Combine for Powerful Gains In Major Hospital Laboratory.***
- ***Point-of-Care: How One Lab Used POCT in Unexpected Places to Substantially Cut Cost-Per-Healthcare Encounter.***

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