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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Less Money for Labs Is International Trend

TOO OFTEN THESE DAYS, labs are asked to accept less money. This is true in the United States and in many developed countries around the world.

Many of you know that the latest version of the Senate health reform bill recently released by Max Baucus (D-Montana) calls for all providers to pay a "fee" as one source of revenue to fund the proposed expansion of healthcare services. In the case of laboratory testing, the Senate bill pencils in laboratory testing for $750 million in annual fees. That would be a unique new source of government revenue and would be assessed even as the same Senate bill mandates a reduction in fees paid for lab testing services. It presents clinical labs and anatomic pathology groups in this country with a revenue double-whammy. *(See pages 7-8.)*

However, compared to what's happening to private laboratory testing companies in New Zealand, U.S. pathologists and laboratory executives should consider themselves fortunate that they still have the opportunity to provide laboratory testing services to patients and physicians. In New Zealand, the government health service, at both the national and local levels, is acting as if "profit" is an element that saps money out of available funding for health services.

Beginning early in this decade, at a regional level, district health boards in some regions began awarding exclusive, multi-year contracts. In these communities, to bid and win, competing private pathology labs had to join together and form a single lab provider company. In return, the government granted the new lab joint venture a monopoly in that market for the term of the contract.

Where it gets interesting is at the end of these monopoly contracts. In the case of Auckland, as that first lab testing contract ended, under questionable bidding circumstances the district health boards awarded the next eight-year contract to a brand new lab company—which had no laboratory and no staff in Auckland to service this contract! This new lab company offered a bid that was 20% lower than what was offered by the existing contract holder. *(See Pages 3-6.)*

As you read this, the patients and physicians in greater Auckland are experiencing the first consequences of this new money-saving lab testing contract, which became effective September 7. Critics will be watching to learn if the district health boards will truly realize the projected reduction in the cost of lab testing, without causing a serious decline in the quality of lab testing services. TDR

Lab Test Fiasco Unfolding In Auckland, New Zealand

District Health Boards scramble to address deficiencies in performance of the new lab provider

CEO SUMMARY: This may be the shortest lab testing contract honeymoon ever. Just ten days after LabTests became responsible for an exclusive, eight-year lab testing contract covering the Auckland area, problems with its service and operation caused District Health Board (DHB) officials to put the lab on notice. DHB employees are also now working inside LabTests to oversee safety and quality assurance. Meanwhile, the press is airing the complaints of patients and physicians.

FAR AWAY IN AUCKLAND, NEW ZEALAND, problems associated with the transition to a new exclusive laboratory contract with an untested laboratory company have become national news.

On September 7, **LabTests**, a division of Australia-based **Healthscope Limited**, assumed responsibility for laboratory testing in the greater Auckland region. Its debut as the exclusive lab testing provider for physicians' offices in the area proved to both a public relations bomb and a major disruption to physicians and patients.

September 7 was the effective date for the controversial and much-contested exclusive eight-year laboratory testing contract between **LabTests**, a division of Australia-based **Healthscope Limited**, and the three District Health Boards that make up the Auckland region.

However, the transition to LabTests from the previous contract laboratory, **Diagnostic MedLabs** (DML), a division of **Sonic Healthcare, Ltd.**, actually happened in three stages. Stage one happened on August 10. On that date, LabTests opened its patient service centers (PSCs) in the Counties Manukau health district.

This area represents about one-third of the daily patients served under the overall lab testing contract. By August 13, the headline in the *New Zealand Herald* was "Long waits for blood tests anger patients," and, since that date, news coverage about the performance of LabTests continued to go against the young company.

Step two happened on August 24, when LabTests initiated service in the Auckland district. These patients represented another one-third of the daily total

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served by this contract. On September 5, the *Herald* was reporting "Stall last Labtests switch, say GPs." Chairman Peter Didsbury of **Procare Health**, an organization which represents 500 general practitioners (GPs) and 400 practice nurses across Auckland (about half of the GPs and nurses in the area), told the newspaper that the final transition to Labtests should be delayed. He said that significant numbers of patients continued to endure long waiting times for tests, even as physicians sometimes failed to get the results of urgent tests within 24 hours.

12,000 Patients Per Day

The third and final stage in the transition happened on September 7, when LabTests opened its PSCs in the Waitemata health district. Now the laboratory was serving up to 12,000 patients per day.

Press coverage only worsened. On September 10, the *Herald* wrote "The Medical Association says Auckland's new community laboratory service is unacceptable and the Government must take action."

This story was also the first to call attention to the negative impact that the transition to LabTests was having on patient care. Peter Foley, M.D., Chairman of the **New Zealand Medical Association** (NZMA), was quoted as saying, "The level of service reported to the NZMA is unacceptable in many respects, resulting in a number of patients not receiving appropriate care when they need it."

LabTests Put On Notice

Developments continued at a swift pace. By September 14, Auckland DHB chairman Pat Snedden announced that, under DHB authority, six senior health officials would be present at LabTests to exercise oversight. These individuals would handle safety and quality assurance and the cost of this would be reimbursed by LabTests. It was also disclosed that the DHB boards not only can terminate the contract with LabTests, but the DHBs have the authority to "forcibly" purchase LabTest's business operation.

One day later, LabTests' CEO was sacked. It was announced that Ulf Lindskog would return to work for Healthscope in Australia. He was replaced by Paul Waterson, who is Chief Operating Officer at Healthscope's pathology division in Australia. Also coming from Australia to help were Dr. John Andrew, Medical Director, of the pathology division, and Healthscope's Chief Medical Officer, Dr. Michael Coglin.

It is ironic that it took the District Health Boards less than 10 days to publicly acknowledge the serious failures of LabTests and put the company on notice that its contract status was in jeopardy. After all, these same government health officials spent almost four years defending all aspects of the changeover from Diagnostic Medlab to LabTests. Officials of the DHBs are on record repeatedly assuring the public, physicians, and the nation, that the transition to LabTest would be well-handled and the savings offered by LabTests justified any risks involved in changing laboratory companies.

Auckland Is Worth Watching

The unfolding events in Auckland are instructive to both laboratory medicine professionals and government health program officials in any developed country around the world. The disruption and potential for patient harm now happening in Auckland demonstrates how quickly a simple change can cause lab testing quality to fall below acceptable standards.

Based on direct site visits to laboratories in New Zealand during the past year and other studies, THE DARK REPORT believes that New Zealand may be the furthest along of any developed country in undermining the integrity of its laboratory testing services. This is one reason why it is important to track the consequences of lab contracting policies like in those in Auckland. TDR

Audacious Lab Contract Shows Downside Risks

Auckland patients and physicians now coping with the "lowest cost" laboratory testing company

CEO SUMMARY: In Auckland, New Zealand, unfolding events may soon reveal the answer to a long-standing question in pathology: is there a point where deep cuts to payment for lab testing causes such a decline in quality and service that other health services undergo disruption? District Health Boards, to save about 20% of their lab budget, replaced a highly-rated lab testing company with a new entrant to Auckland. Since the changeover on September 7, patients and doctors have voiced their complaints.

By Robert L. Michel

EVENTS NOW UNFOLDING in Auckland, New Zealand, represent probably the single most audacious laboratory contracting project in a developed country during the past few decades.

In recent weeks, the negative consequences of this lab testing contract have become visible to patients and physicians in the Auckland region. Problems with the new lab testing provider are featured daily in the national news.

Contract Award In 2006

It was back in 2006 when, to further drive down the cost it paid for laboratory testing, bureaucrats at the three District Health Boards (DHBs) in Auckland awarded an exclusive, eight-year contract to **LabTests**, a division of **Healthscope Limited** of Australia.

Two problems were immediately obvious to any informed observer. The first problem was reimbursement. LabTests, as the winning bidder, had offered a price that was 20% less than the existing laboratory provider. Experienced laboratory professionals wondered how LabTests would survive on that reimbursement, since, among other things, it would have to spend money to build and staff a lab in Auckland that it didn't have at that time.

The second problem is more interesting. The plan to implement the new, exclusive, eight-year lab testing contract would require LabTests to build a lab facility big enough to test 12,000 patients per day. On the contract start date, which turned out to be September 7, 2009, it would activate this empty new lab facility and start testing. Call this a "cold start," as contrasted with a laboratory that is already in operation and must expand to absorb additional specimens ("warm start").

On paper, this plan might appear reasonable. But, to the knowledge of THE DARK REPORT, there is no precedent for the "cold start" of a lab that would immediately handle 12,000 patients per night. In fact, in the United States, a lab that size would rank in the top tier of labs by daily test volume.

Thus, both LabTests and the DBHs were committed to a "mission impossible." LabTests would have to build a brand new

lab facility, as well as patient service centers. They would have to install new analyzers and instruments, then validate each instrument's operation. Similarly, each of the hundreds of assays to be run in the lab would have to be validated and correlated.

At the same time, LabTests would have to implement a laboratory information system (LIS) along with the interfaces required to support electronic test ordering and lab test reporting with clinics and physicians' offices. Of course, hundreds of experienced laboratory professionals would have to be hired and oriented to the laboratory's scientific protocols and operational procedures.

Did Auckland's District Health Boards violate the public trust by awarding an exclusive multi-year contract to a new laboratory company which had neither the laboratory facility nor the technical and operational staff in Auckland—and agreeing to a "cold start" of that laboratory on September 7?

From first public news of the contract award back in 2006, DHB officials were warned by a range of experts that their decisions were likely to: 1) put the health of thousands of patients at risk; 2) disrupt the smooth daily functions of a respected regional healthcare system; and 3) cause more money to be spent coping with the problems resulting from this audacious decision than would be realized from the expected savings.

➤Events Prove Critics Right

Now the events of recent weeks are proving the critics of the contract award and "cold start" approach to be right. Even though LabTests was allowed to avoid a "cold start" by starting transitional service to some areas on August 10 and August 24, problems surfaced immediately.

As reported by various press sources in New Zealand, these problems are numerous, exactly what an experienced pathologist or laboratory expert would predict.

For example, to survive on 20% less money than the previous contract lab, LabTests reduced the number of patient service centers in Auckland from the 81 sites maintained by DML to just 56 collection centers. That's a 30% reduction in sites and contributed to overcrowding and long waits as LabTests became operational.

➤Recruiting Outside Auckland

Next, to hire the hundreds of people needed to staff the new laboratory, LabTests recruited abroad. Patients were quick to complain about phlebotomists. Complaints included a lack of skill, collecting the specimen wrong so the patient had to return a second time, and a lack of good language skills.

Pathologists may be interested in how LabTests organized its medical staff. DML had 25 full-time pathologists. As reported in the *New Zealand Herald*, LabTests planned to start with 17 pathologists. Many of these were recruited overseas. On September 15, the Medical Council announced that six of the pathologists listed on the LabTests web site were not yet registered to practice in New Zealand.

Turning to clinical accuracy, the press is full of stories about cancer patients waiting weeks to get a diagnosis, of delayed access to pathologists to discuss test results, of lengthy waits for test reports, and of patients getting lab test results for another person.

Now that LabTests is operational and the inadequacies of its testing operation are visible to patients and physicians, the attention will shift to the District Health Boards. LabTests will get additional time to fix the problems. But what if these fixes are not enough? Anxious to protect their credibility and save face, it is unlikely that the DHBs would do something as simple as voiding the LabTest contract and signing a new contract with Diagnostic Medlab.

Unfortunately, regardless of how the DHBs resolve the current problems with lab testing in Auckland, they have already eliminated effective competition in lab testing from the region. That fact will greatly limit their options in coming years. TDR

$750 Million Lab Test Tax Proposed in Senate Bill

Latest Senate health reform bill includes tax on lab tests, along with reduction in reimbursement

CEO SUMMARY: A bill that may be the U.S. Senate's framework for reforming the U.S. healthcare system calls for a tax of $750 million per year to be paid by lab testing companies. The proposed bill also calls for a reduction in Medicare reimbursement for lab testing. One positive element was that reinstatement of the Medicare lab test co-pay was dropped from this version of the health reform bill. THE DARK REPORT provides details of how the Senate bill would determine the amount of tax each lab testing company would pay annually.

When MAX BAUCUS (D-Montana), Chairman of the Senate Finance Committee, released his healthcare reform bill to the press earlier this month, it provided insights into how Senate leaders want to finance health reform.

For the laboratory testing industry, the news was not good. This version, considered to be an important road map to health reform, contains two significant details that could be detrimental to clinical labs. First, the bill calls for a significant new tax to be assessed on clinical lab testing. Second, the bill calls for cuts in Medicare fees that labs currently earn on lab testing services.

Investors understood the implications of these legislative proposals. Kirell Lakhman of *genomeweb.com* blogged that "Investors in clinical labs are right to be concerned by the government's plan to tax the fecal-occult blood out of them [the lab companies]." Writing on September 10, Lakhman noted that, since what he called the "Baucus Ruckus" two days earlier, the share prices of **Quest Diagnostics Incorporated**, **Laboratory Corporation of America**, and **Bio-Reference Laboratories, Inc.**, had declined by as much as 2.3%, 2.0%, and 1.6%, respectively.

The proposals in the new bill caught the attention of the **American Clinical Laboratory Association** (ACLA). "Senate Finance Committee Chairman Max Baucus' plan to impose $750 million in taxes on clinical laboratory testing services—on top of other cuts—translates into a disproportionate cut for laboratories and will damage efforts to enhance prevention and wellness, and raise healthcare costs," noted Alan Mertz, ACLA President in a written statement.

"The tax unfairly targets the clinical laboratory industry among providers, which includes about 40,000 labs providing a myriad of critical health services to patients across the nation," Mertz commented. "When the $750 million in new fees are added to other cuts in the proposal, America's clinical labs could be facing cuts several times that of other providers."

The second problem for medical laboratories in the Baucus bill are cuts in Medicare spending for lab tests. This con-

Understanding How the Senate Bill Would Calculate the Tax to Be Paid By Laboratory Companies

AS DEFINED IN THE PROPOSED LEGISLATION released by the Senate Finance Committee, a fee would be imposed on any "covered entity" offering clinical laboratory services in the United States.

"The aggregate fee on the clinical laboratory sector would be $750 million annually, beginning in 2010," states the bill, which further explains that the aggregate fee would be apportioned among labs based on each lab's relative market share of covered domestic laboratory service revenue in the previous year and would be need to be paid annually.

"A covered entity would be defined as any company that provides services for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings," the bill said. The term "covered entity" would include a parent company, its affiliates, and other related parties, the bill said.

The "covered domestic laboratory service revenue" would include revenue from providing laboratory services in the United States. Notably, laboratory services performed by a hospital for inpatients of the hospital would be excluded from this tax.

The bill would ask the Secretary of the Treasury to require any covered entity to file an annual report of its covered domestic laboratory service revenue for the prior calendar year. The secretary would establish individual assessments based on each company's relative market share. "A covered entity's relative market share would be the entity's covered domestic laboratory service revenue as a percentage of the total reported covered domestic laboratory service revenue for all covered entities," the bill said.

Small labs that generate revenue of less than $500,000 would be exempt. "In determining each covered entity's relative market share, covered domestic laboratory service revenue will be taken into account as follows: 0% of revenue up to $500,000 and 100% of revenue over $500,000," the bill said. The Baucus bill also would allow the fees paid by labs under this provision to be deductible for U.S. income tax purposes.

tinues a 25-year pattern of significant underfunding of laboratory testing services by federal health programs.

"Overall, Medicare payment amounts for clinical laboratory services have been reduced by about 40% in real, inflation-adjusted terms between 1984 and 2004," Mertz explained. "Congress has acted to completely eliminate the annual payment update for clinical labs in 10 of the last 12 years. Since 2000, labs have received the smallest cumulative update of any provider in Part B of Medicare, only 5.6% compared to 12% for physicians and 34% for hospitals."

Against the news of a new $750 million tax on lab testing and a reduction in reimbursement for lab services, there was at least one favorable development. Earlier this summer, Baucus' committee had considered reinstating the lab test co-pay requirement for Medicare patients. The proposed bill did not contain that provision.

Given the rancorous national debate, pathologists and lab executives should expect much more to happen before both houses of Congress vote on their versions of health reform bills. **TDR**

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Textbook Marketing Fuels Demand for BRCA Test

Direct-to-consumer advertising is one tool Myriad uses to drive sales of cancer risk testing

CEO SUMMARY: In today's lab testing marketplace, the hot ticket is to introduce a proprietary or patent-protected molecular test for cancer. The sales and marketing model inspiring many of these new lab testing companies is that used by Myriad Genetics, Inc. since it introduced its BRACAnalysis test for breast cancer back in 1996. A new report by William Blair & Company, LLC, analyzes Myriad's successes. Pathologists and lab administrators will find useful insights about techniques they can use to market their own specialized lab testing services.

IN THE LABORATORY INDUSTRY, one of the fastest-growing sectors is that of proprietary or patent-protected diagnostic tests. This is particularly true for predictive genetic tests that target specific types of cancer.

At the head of this class is **Myriad Genetics, Inc.**, of Salt Lake City, Utah. In 1996, it launched its patent-protected BRAC*Analysis* assay. Designed to predict a patient's risk of breast and ovarian cancer based on mutations in the BRCA1 and BRCA2 genes, this assay is a major source of revenue for Myriad Genetics. It also markets six other genetic tests that either evaluate a patient's risk for developing colorectal cancer and melanoma, or assess a patient's response to certain oncology drugs.

As one of the first companies to launch a predictive genetic test for a specific type of cancer, Myriad Genetics now has more than 13 years of results and data. In fact, Myriad may be one of the best business case studies on how to successfully launch and build demand for a genetic test that is predictive for a specific type of cancer.

Of course, Myriad's patent on the BRCA genes is not without controversy. Early this year, on May 12, the company was sued by the **American Civil Liberties Union** (ACLU) and the **Public Patent Foundation**. The lawsuit was filed in United States District Court for the Southern District of New York in Manhattan, on behalf of four laboratory associations and numerous individual plaintiffs. The lawsuit charges that the patents held by Myriad and the **University of Utah Research Foundation** are unconstitutional and invalid.

$3,000 Predictive Genetic Test

Meanwhile, Myriad continues to build its business and promote its BRAC*Analysis* test, for which it charges $3,000. One source of useful insights into Myriad's marketing strategies comes from a report recently issued by two financial analysts at **William Blair & Company, LLC**. Blair is bullish on Myriad's prospects for continued strong growth in specimens, revenue, and profits.

"Myriad's strong intellectual property position (consisting of 312 issued patents,

including those the company owns and has licensed) has afforded the company with a monopoly position, particularly for its BRAC*Analysis* test for inherited breast and ovarian cancer risk," stated the report, which was written by Blair analysts Amanda Murphy and David Kittle. "This competitive advantage has allowed Myriad to sustain pricing power (including the ability to implement price increases) as well as high gross margins (80%-plus)."

Murphy and Kittle believe that several elements work in Myriad's favor. Demographics is one such factor. "Myriad operates in large, growing markets, which are driven by demographics (an aging population that is living longer) and continued growth in the prevalence of cancer (the number of patients living with the disease)," they wrote.

A second factor is that its proprietary laboratory tests are supported by strong clinical data. This has fueled Myriad's growth in two significant ways. One, it facilitated the incorporation of Myriad's cancer predisposition tests into many professional organizations' clinical practice guidelines. In turn this encouraged adoption by physicians (particularly in the oncologist community).

➤Screening Guidelines

For instance, the Blair report notes how, in April, the **American College of Obstetrics and Gynecology** (ACOG) updated its guidelines to include screening for BRCA mutations for patients who have not yet been diagnosed but who have a family history of cancer. Myriad's BRCA screening test also has been recommended by the **American Society of Clinical Oncology**, the **National Comprehensive Cancer Network**, and the **Society of Gynecologic Oncologists**.

The third factor is how such clinical data have supported broad reimbursement by payers. Some 130 million patients are insured by managed care plans that cover the BRAC*Analysis* test, the report said. And, among insurers, such as **Blue Cross Blue Shield**, that do not have formal contracts with Myriad, the company still gets a high rate of reimbursement of 92% of the list price from payers for its tests.

The fourth factor identified by Murphy and Kittle is that Myriad is working to expand use of the BRCA test by the "underpenetrated" ob-gyn market. The Blair analysts observed that "Myriad has focused on testing for patients diagnosed with cancer; however, cancer risk assessment for the asymptomatic population is the larger opportunity."

➤More Sales Reps For Growth

Myriad's sales and marketing strategies were identified in the Blair report, providing pathologists and lab executives with useful insights on how the company expects to expand use of its BRAC*Analysis* and other tests.

Myriad will attack the ob-gyn segment by expanding its sales force and launching advertising campaigns in the Midwest. "We believe Myriad is still early in its adoption by ob-gyns and expect increased use in these markets to help sustain longer-term earnings growth of 25% or more," the report said. "The pull-through opportunity in the ob-gyn market and the continued adoption by oncologists should help the company diversify beyond BRCA1/2 screening and sustain longer-term earnings growth of 25% or more."

The sales force expansion will be substantial. In the first quarter of this year, Myriad doubled the number of salespeople who call on ob-gyns by having 100 of its 250-member sales force focus specifically on the ob-gyn market.

The company also accelerated hiring of sales staff. It brought in 50 more sales representatives to focus on the ob-gyn market. According to Blair, Myriad currently has a total of 300 sales reps; 150 are

Myriad Uses Multiple Marketing Strategies To Build Demand for its Genetic Cancer Test

CHART 1: Annual Volume of BRAC*Analysis* Tests

Chart at right was prepared by Blair & Co. and shows the annual number of BRAC*Analysis* tests at Myriad Genetics since 2000, plus the estimate for volumes through 2011. Since 2006, Myriad has been educating physicians about how to use this test on asymptomatic patients with a familial risk.

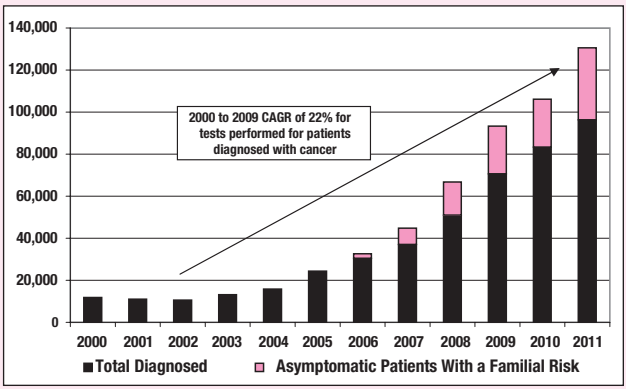


CHART 2: Annual Percentage Rates of Diagnostic Revenue Growth

Chart below was prepared by Blair & Co. to present the percent rate of growth each year since 2000 in Myriad's revenue from diagnostic testing, along with Blair's estimates through 2011. Inset boxes note timing of significant events, including direct-to-consumer advertising campaigns.

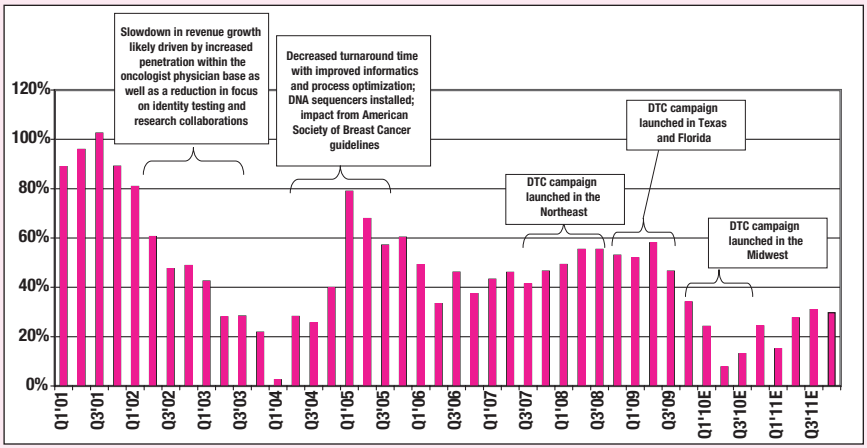
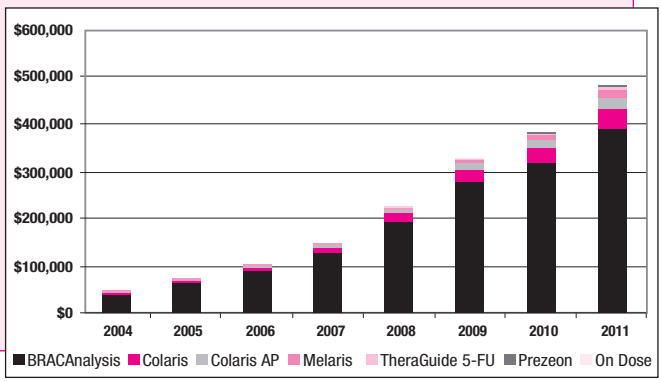


CHART 3: Annual Revenues for Individual Genetic Tests

Chart at right was prepared by Blair & Co. and shows Myriad's annual revenue for the BRAC*Analysis* test plus other assays since 2000, along with Blair's estimate of revenue through 2011. This chart shows why the BRAC*Analysis* test remains Myriad's major revenue source.

Charts prepared by William Blair & Co.



assigned to the ob-gyn market and 150 are focused on the oncology market.

Given that it usually takes about four to six months for these sales professionals to break even, the Blair analysts predict they could contribute to Myriad's profits in the first half of 2010.

Regional Marketing

Lab managers and pathologists may consider that the most interesting factor in the Myriad story is how it uses regional marketing campaigns to target consumers and physicians. In these campaigns, the company first conducts a five- to six-month physician education component. This is followed by five- to six-month long direct-to-consumer (DTC) advertising program.

"Myriad's previous DTC campaigns (launched in the Northeast in 2007 and in the South in 2008) have been successful in driving ob-gyn use of testing," wrote Murphy and Kittle, who estimate that DTC advertising in the Northeast helped Myriad increase the number of physicians ordering the test in that region by 78%.

At this time, physician and DTC marketing campaigns are taking place in the Midwest, an area that represents 15% of Myriad's current revenues. The Blair report notes that Myriad plans to end this effort on March 31, 2010. Myriad also relaunched its DTC campaign in Texas and Florida. It began August 17 and is scheduled to run through the end of the year.

13-Year Track Record

Myriad Genetics now has 13 years of sustained success in building demand for its high-priced BRAC*Analysis* test. For that reason, any number of biotech companies and equity investors consider it the prototype for how a company should launch and support a campaign to promote a patent-protected or proprietary genetic test.

This is equally true for anatomic pathology (AP) groups. Myriad's experience over the past 13 years provides evidence that employing sales reps to build AP case referrals can be a profitable use of capital. Many community hospital-based pathology groups are reluctant to fund such a sales program, even as Myriad and a number of other national pathology companies find it profitable to send sales reps into their communities to solicit case referrals.

Another area in which Myriad is a pioneer is the use of direct-to-consumer advertising to build awareness of a diagnostic test. It conducted its first DTC campaign for the BRAC*Analysis* test between September 2002 and February 2003. Advertisements were run in Denver and Atlanta. At the time, Myriad's willingness to advertise a predictive genetic test for cancer to the public caused quite a stir among healthcare ethicists.

Direct-To-Consumer Ads

Those concerns turned out to be unfounded. Meanwhile, Myriad likes the results generated by these DTC advertising campaigns. For the past seven years, it has conducted a series of regional DTC promotions.

This is evidence for pathologists and lab managers that DTC advertising campaigns can be a cost-effective way to build public awareness about a predictive genetic test for cancer. In coming years, the laboratory testing profession can expect to see other companies with proprietary diagnostic tests use DTC advertising campaigns as a way to increase case referrals.

Finally, Blair analysts Murphy and Kittle believe that demand for Myriad's diagnostic tests will remain strong. They predict double digit growth in specimen volume and revenues for Myriad during 2009 and through 2011. They estimate that the company, which had molecular test revenue of $43.3 million in 2004, will generate revenue of $481.4 million in 2011. TDR

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Clinical Study Update

Some Docs Fail to Tell Patients About Critical Results 25% of Time

PRIMARY CARE PHYSICIANS often do not report patients' lab test results, according to a recent study of 5,434 patients aged 50 to 69. That won't be news to most lab directors and pathologists.

But there is something new and useful in this study. Its findings are revealing for three reasons. One, it involves a large sample size of patients. Two, it is believed to be the first study to estimate the "failure to inform" rate across a variety of laboratory tests and types of practice. Three, this research represents continued progress toward holding physicians accountable to take the appropriate steps to produce an accurate diagnosis and report test results promptly to patients.

Study leader was Lawrence P. Casalino, M.D., Ph.D., MPH, Division Chief in the Department of Public Health at **Weill Cornell Medical College**, in New York City. "Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results," was published on June 22 in *The Archives of Internal Medicine.*

Failure To Inform Patients

In the case of failure to inform patients of clinically significant abnormal test results or failure to document that the patients were informed, the average rate was 7.14%, or 1 of every 14 tests. However, the failure rate varied from 0% to 26%, or as many as one in four tests! One interesting finding is that those medical practices using what's called a partial electronic medical record system (meaning a combination of paper and electronic records), had the highest failure rates of reporting test results to patients.

By contrast, researchers did not find a significant difference between practices that had a complete EMR and those that used paper records. Another study finding is that most practices did not use all of the relatively simple processes suggested in the literature as basic to managing test results. In particular, most practices did not have explicit rules for notifying patients about results and many told patients that—if they did not learn about their test results—they should assume that "no news is good news."

Improving Patient Safety

This study by Casalino and his colleagues about how often physicians fail to report critical results to the patient or document that the patient was notified is a welcome development for the lab testing profession. It shows how the focus on patient safety, now firmly entrenched in the hospital setting, is now beginning to raise its profile in physician office settings.

As well, this study supports the developing effort to hold physicians accountable for diagnostic errors. As reported earlier this year, physicians at Johns Hopkins showed that diagnostic errors—including missed, wrong, or delayed diagnoses—account for 40,000 to 90,000 deaths annually, *(See TDR, April 6, 2009.)*

Laboratory administrators and pathologists should welcome clinical studies of this sort. These are early efforts to address deficiencies in the pre-pre analytical and post-post analytical steps (outside the laboratory), where physicians often fail to use laboratory test results to the maximum benefit of patients. TDR

Medicare Pays Doctors To Switch to E-Prescribing

➤Medicare incentive adds 2% for e-prescribing in 2009 and 2010, then changes to 1% for 2011

➤➤CEO SUMMARY: It's a major step on the road to integration of healthcare informatics. During the next few years, the Medicare program is offering financial incentives to encourage office-based physicians to adopt e-prescribing. This is a positive development for local laboratories and hospital lab outreach programs. Early-adopter labs are already taking steps to enable e-prescribing as part of the electronic lab test order/results reporting systems they offer to client physicians.

MEDICARE'S EFFORT TO ENCOURAGE physician use of electronic prescribing includes a financial incentive during the next few years. That is one reason why laboratory informatics companies are incorporating e-prescribing into their electronic lab test ordering and results reporting systems.

Clinical laboratories are recognizing how this opportunity can create competitive advantage. Early-adopter labs are beginning to offer office-based physicians an e-prescribing capability that is a part of the lab test order/results reporting system they provide to office-based physicians.

However, as with any government program, there are requirements that must be met. Laboratories wanting to incorporate an e-prescribing capability for their office-based physician clients need to understand the parameters of the financial incentives offered by the **Centers for Medicare and Medicaid Services** (CMS).

"Additional Medicare reimbursement to physicians who prescribe electronically has definitely caught their interest," stated Ravi Sharma, CEO of **4Medica, Inc.**, based in Culver City, California. "Physicians who adopt e-prescribing will receive a 2% increase for Medicare patients in 2009 and 2010. That bonus will be 1% in 2011.

"Physicians need only take two simple steps to qualify for this Medicare e-prescribing incentive," explained Sharma. "First, at least 10% of the physician's patient population must be Medicare beneficiaries. Second, the physician must report using CMS' new ePrescribing G Codes for at least 50% of Medicare visits or consultations during the year."

➤E-Prescribing System

Sharma's firm offers a unique e-prescribing solution that correlates patient lab data when ordering medications and alerts physicians to changes in lab values.

"Lawmakers wanted to help physicians offset the costs of converting patient records to a digital format," said Sharma. "This e-prescribing bonus is designed with both incentives and disincentives.

"In 2009, 2010, and 2011, physicians using e-prescribing will get an added payment from Medicare," he continued. "However, physicians who are not

onboard by 2012 will see their Medicare reimbursement reduced by 1% until 2014, when the penalty rises to 2%."

In another sign of the progress toward integration of health informatics, Medicare is requiring that any e-prescribing system used by physicians must be certified by **SureScripts**, which operates a national pharmacy information system network. "The e-prescribing system must identify drug-to-drug interactions; access patient medical history for potential contraindications; and provide formulary and benefits information, including availability of less expensive alternatives and generics," stated Sharma.

About 70,000 community pharmacies are currently connected to the SureScripts network. Anticipating the Medicare e-prescribing bonus, in 2008, the number of physicians using this service doubled, when 74,000 physicians, or 12%, came onboard for electronic prescribing, compared to 36,000 the previous year. In 2008, about 4% of prescription volume was ordered electronically. SureScripts predicts that, by 2012, 30% of the total 2.1 billion Rx volume—or 672 million prescriptions—will be electronically ordered.

Revisions to Medicare Laws

In Sharma's view, advances in informatics technology, along with revisions to the Stark Law (the Ethics in Patient Referral Act of 1993) and the Medicare and Medicaid anti-kickback law, are converging. In turn, this convergence is creating new business opportunities for local labs and hospital lab outreach programs to compete more effectively against the national laboratory companies.

"Labs focused on providing competitive outreach must go beyond lab connectivity and offer value added solutions to earn physicians' loyalty and help improve care," advised Sharma. "Stark Law exceptions and anti-kickback safe-harbors now allow laboratories to offer technology that physicians can use to not only connect with labs and EMRs, but also offer e-prescribing. This provides physicians with the convenience of

E-Prescribing Can Reduce Medical Errors, Save Costs

"IT WAS THE POTENTIAL TO REDUCE MEDICAL ERRORS that encouraged the Centers for Medicare and Medicaid Services to make e-prescribing a priority project," stated Ravi Sharma, CEO of 4Medica, Inc., of Culver City, California. "E-prescribing can have a tremendous impact on both patient safety and costs." Sharma cited numerous studies to make his case.

A study by the **Institute of Medicine** (IOM) found that 1.5 million adverse drug events (ADEs) per year are preventable. Other studies put the number higher. A study commissioned by the **Pharmaceutical Care Management Association** (PCMA), the national association of pharmacy benefit managers, estimated that e-prescribing could prevent about 3.5 million ADEs and 585,000 hospitalizations annually. The **Center for Information Technology Leadership** increased the estimate to 8.8 million ADEs in ambulatory care alone.

A report from the journal *Quality and Safety in Health Care*, in fact, indicates that the rate of prescription errors among physicians is 70%, of which 50% could be prevented with e-prescribing. The study involved 440 physicians. Pharmacists caught 40% of errors, but of those reaching patients, 8% required an intervention and 3% resulted in hospitalization. The PCMA report also estimated $22 billion yearly in savings for federal insurance plans and $56 billion for all payers

On the physicians' side, a report issued by the **Medical Group Management Association** (MGMA) estimated that e-prescribing could save a practice of 10 physicians an average of $19,444 a year by eliminating staff time needed to handle calls from pharmacists to clarify prescriptions or discuss potential errors.

When Can a Lab Pay For Doctor's IT System?

EXCEPTIONS TO THE STARK LAW and safe harbors under the Medicare and Medicaid anti-kickback law for ePrescribing and electronic medical record (EMR) allow laboratories and other providers to donate certain software to physicians. These software technologies must connect, have EMR as their primary functionality, and contain e-prescribing capabilities.

Jane Pine Wood, a partner in the Boston-area office of the law firm McDonald Hopkins, offers the following guidelines for compliance with requirements of EMR exceptions:

1. Laboratories and other providers can pay up to 85% of the cost of qualifying EMR software. Physicians must contribute at least 15% of the cost upfront.
2. Donations are limited to purchase of new EMR software. Labs cannot reimburse physicians 85% of the cost for the same or comparable software they already own, nor can software have other primary functionality, such as billing or appointment scheduling.
3. No cost-sharing is permitted for hardware.
4. Software must be "interoperable", and the rules provide that parties can satisfy this requirement by donating EMR software that is certified by the **Certification Commission for Healthcare Information Technology** (CCHIT). The regulatory definition of interoperable is: able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.
5. Labs cannot make their software donation contingent upon physician referrals.
6. The arrangement is set forth in a written agreement that identifies criteria that include: items and services provided, the donor's cost, and the amount of the physician's contribution.

online order entry for both prescriptions and lab tests."

However, before a laboratory offers to pay for such technology, it must comply with several requirements. "Under the rules, labs can donate up to 85% of the cost for EMR software," stated Jane Pine Wood, a partner at McDonald Hopkins. "Physicians must pay 15% up front. The lab can only pay for new software that has EMR capability as its primary functionality, along with the e-prescribing function. Labs cannot reimburse physicians for EMR software they already own, or pay for software that does other primary functions, such as billing or scheduling appointments." *(See sidebar on this page.)*

➤ Private Payer Incentives

More evidence of the commitment to e-prescribing are the actions of major health insurers. Several have initiated financial incentives to encourage physicians in their provider networks to adopt e-prescribing. For example, **WellPoint, Inc.**, the nation's largest insurer, pays physicians up to 6% above the regular fee schedule for prescribing electronically. Similarly, **Blue Cross Blue Shield of Massachusetts** subsidizes electronic subscriber costs for one year.

Because e-prescribing systems—when properly designed—can be used by physicians without major changes to their daily work flow and practice patterns, it is likely that adoption will be relatively swift. In turn, widespread physician adoption makes it imperative that all clinical labs be prepared to integrate their informatics offerings with this capability.

Intelligence briefings on the following pages address how two informatics vendors are working to add e-prescribing capabilities to the lab test ordering and results reporting systems they sell to clinical laboratories. **TDR**

—P. Kirk

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Informatics Update

E-Prescribing Functions that Labs Can Offer Office-Based Physicians

IN RESPONSE TO MEDICARE AND PRIVATE PAYER efforts to increase physicians' use of e-prescribing, **4Medica, Inc.**, of Culver City, California, was one of the first laboratory informatics vendors to add an effective e-prescribing capability to its lab test order and results reporting system.

"As physicians adopt e-prescribing, it is a timely opportunity that laboratories can leverage to their competitive benefit," stated Ravi Sharma, CEO of 4Medica. "Having a user-friendly e-prescribing service integrated into the lab test order and results reporting system can improve productivity of the physician and his office staff. More importantly, use of e-prescribing plays an important role in reducing prescription errors and negative drug interactions.

"There is another reason why clinical labs and pathology practices should want to offer e-prescribing as part of their electronic interface with referring physicians," continued Sharma. "The build up in e-prescribing is simultaneously expanding physician use of computerized physician order entry (CPOE) and online EMR [electronic medical record] connectivity.

Fully Integrated Informatics

"This represents important progress toward the goal of fully integrated healthcare informatics, particularly as it supports the universal digital health record (DHR)," he stated. "Labs must constantly update their LIS and informatics services to support this ongoing integration."

4Medica's proprietary lab outreach application, LabIHR, interfaces with a contiguous suite of applications. "MedsIHR is our e-prescribing solution," said Sharma. "It is one module that works with our LabIHR, which allows physicians to send lab orders and receive results electronically. Other integrated applications include specimen labeling, some lab management functions, electronic transfer of imaging test orders and results, and even an application that allows the physician to remotely monitor progress of a hospitalized patient. Our system is designed so the doctor doesn't have to log in and out, but can navigate from application to application with a single click." TDR

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E-Prescribe Functions

FOR LABS INTERESTED in providing their client physicians with an e-prescribing solution, Sharma provided a list of functions that can be performed by such a system. They include:

- Eligibility and formulary checking
- Automatic alerts and notifications
- Drug to drug interactions
- Drug to allergy interactions
- Drug to lab interactions—available in real time, both at the time of placing medication orders and when alerting physicians to changes in lab values.
- Graphing—multiple lab analytes and medications are graphed on a single graph indicating the relationship between lab results and medications.
- Create common lists of frequently ordered medications
- Select formulary preferred alternative drugs
- Access patient's historical medications
- Print, fax, or electronically transmit prescriptions
- Route prescriptions to patient-preferred or practice-preferred pharmacies

Informatics Update

E-prescribing Is Example of Need For Labs to Support Connectivity

EFFORTS TO MOTIVATE PHYSICIANS to adopt e-prescribing is just one part of a wider trend in healthcare. The drive to achieve full integration of health informatics is gathering momentum.

"By itself, the need for clinical laboratories to support e-prescribing is becoming an important competitive differentiator in the market," observed Robert D. Atlas, President and CEO of **Atlas Medical** in Calabasas, California. "But at a higher strategic level, adoption of e-prescribing is a sign of the more important trend in healthcare informatics—full interconnectivity between providers.

Competitive Differentiation

"For example, I encourage labs to go one step further with connectivity," he said. "Merging of prescriptions with diagnostics and radiology is a tremendous opportunity for labs to provide doctors expertise on the pre- and post-analytic sides. It also differentiates the laboratory from its competitors.

"Laboratories have always had a consultative relationship with their referring physicians," he added. "So this is a simple extension of what labs have always done.

"You might say that interconnectivity is the change agent," explained Atlas. "With more physicians using electronic medical records (EMRs), interconnectivity is what allows real time data to feed in and out of the patient's EMR file. Laboratories, as a primary source of much important diagnostic information, must be ready to support the needs of their physicians for enriched data, delivered electronically.

"At Atlas Medical, our approach is to provide laboratories with informatics systems that are highly flexible," stated Robert Gregory, Senior Vice President of Corporate Strategy for Atlas. "This open configuration supports other vendor products in the marketplace as well.

"For instance, we partner with best of breed providers to deliver integrated e-prescribing with our system, so when a physician already uses an e-prescribing product they like, we can integrate it into our application," he noted. "Labs must work with these physicians and not disrupt their work flow. We engineer our products so they can be customized to the specifics of a lab's unique operational needs or a physician's workflow and preferences."

Suggesting that labs should consider partnering with third parties, Atlas explained, "From an IT perspective, labs must manage and connect with multiple disparate systems, which requires a 'connected care capability' to deal with all the different systems in place."

In a healthcare environment marked by different vendors and interconnectivity, Atlas has another recommendation for lab directors and pathologists. "As your lab connects and interfaces with physicians' offices, keep your lab's brand in front of the physicians and their staffs.

Lab Branding In Digital Age

"We achieve this for our laboratory clients by keeping the lab's brand visible in a wired world," commented Atlas. "One way is by auto-printing the lab's brand on requisitions, labels, ABNs (advanced beneficiary notices) and custom formatted results reports." TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Dover, Delaware, entrepreneur pathologist Ray Sukumar, M.D., earned a unique distinction. Earlier this summer, Sukumar was granted a patent for his unique design of a compact histopathology laboratory in a standard delivery van. That accomplishment earned recognition by the **Delaware Economic Office**. Sukumar, who founded **Doctors Pathology Service** (DPS) in 2003, has created a new business model for general community pathology. This business model features "pathology at the point of care." DPS pathologists deliver anatomic pathology services at the physician's office or ambulatory surgery center (ASC), using the mobile histopathology laboratory. *(See TDR, March 12, 2007.)*

MORE ON: New Patent

Sukumar's patent covers the design of what he calls "MICS." This stands for Mobile Intraoperative Consultation Service. The mobile histopathology laboratory is CLIA-accredited. By taking pathology services directly to the location where the physician treats the patient, DPS has generated strong physician loyalty. For the past six years, it has been one of the fastest-growing pathology businesses in Delaware and surrounding states.

UCSF AND ABBOTT PARTNER TO IDENTIFY UNKNOWN VIRUSES

Banding together, the **University of California, San Francisco** (UCSF) and **Abbott Laboratories** formed the "UCSF Viral Diagnostics and Discovery Center" at the beginning of the summer. This non-profit center will "expedite virus discovery in acute and chronic human illnesses, including outbreaks and rare and unusual diseases." A key tool in this effort is the ViroChip. This micro-array-based system was developed by two UCSF professors. One is molecular biologist Joseph L. DeRisi, Ph.D., and the other is Donald Ganem, M.D., who teaches microbiology and immunology.

ADD TO: VIRUS ID

In 2003, as the SARS outbreak commenced, DeRisi received a specimen from the **Centers for Disease Control** (CDC). In a matter of hours, he identified and characterized the virus through the use of the microarray system he had developed. He was one of the first in the world to accurately characterize the SARS virus. *(See TDR, April 14, 2003.)*

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 12, 2009.