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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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Mergers Create Health Insurance Oligopoly

WITH EACH ROUND OF ACQUISITIONS involving the nation's largest health insurers, more power concentrates into the hands of ever-larger corporations. For example, just two companies, **WellPoint, Inc.** and **UnitedHealth Group, Inc.**, now insure one-third of the 150 million Americans who have some form of private health insurance! In the short term, these acquisitions probably mean more difficult contract negotiations for laboratories and pathology group practices.

That's because a national oligopoly is emerging in the health insurance industry. As laboratorians who took economics in college know, an oligopoly is "a market in which control over the supply of a commodity is in the hands of a small number of producers and each one can influence prices and affect competitors." *(From www.wordreference.com.)*

I believe the health insurance industry is currently evolving into a national oligopoly, supported by near-monopolies in selected cities. It is similar to the national oligopoly that's developed in lab testing provided to office-based physicians, dominated by the two blood brothers. Also, there is the airline industry. Nationally, a handful of airline companies dominate. That is the oligopoly. However, in certain cities where an airline operates a hub, it holds a near monopoly. **Northwest Airlines** in Detroit, **American Airlines** in Dallas, and **USAirways** in Charlotte are well-known examples.

So the bad news for the laboratory industry is that consolidation in the health insurance industry—the oligopolistic marketplace now emerging—will give insurers even greater power during contract negotiations with physicians. Just as the major airlines raise and lower air fares with amazing synchronicity, so also will the ever-dwindling group of major payers offer similar reimbursement terms to physicians in their provider networks. By understanding some of the characteristics of oligopolistic behavior, shrewd pathologists and lab directors will do better when negotiating contracts against these health insurance behemoths.

Despite the short-term negative consequences of ongoing consolidation among the nation's largest health insurers, over the long term, I predict the growth of consumer-directed health plans (CDHP) will not only erode some of the the market power of these payers, but may render much of their current business organization obsolete. TDR

Payer Consolidation: WellPoint Buys into NYC

That acquisition motivates Group Health and HIP of New York to agree to merge

CEO SUMMARY: Acquisition by acquisition, the health insurance industry is consolidating. Wellpoint, Inc., already the nation's largest health insurer at 28 million members, is acquiring WellChoice, Inc. and adding another 5 million members to its total. One consequence of this consolidation wave is to concentrate greater negotiating power into the hands of fewer, but larger, private payers.

IN THE LATEST ROUND of consolidation among health insurance companies, New York City has been the regional market of choice.

On September 27, **Wellpoint Inc.** announced a $6.5 billion-dollar deal to acquire **WellChoice, Inc.** These two insurance companies are well-known to clients and readers of THE DARK REPORT by other names. Wellpoint, based in Indianapolis, Indiana, used to be called **Anthem, Inc.** WellChoice is the owner of **Empire Blue Cross Blue Shield**, which serves members in the New York City metropolitan area.

The WellChoice acquisition adds 5 million members to Wellpoint's existing 28 million members. At 33 million members, WellPoint remains the nation's largest insurance company. With this acquisition, WellPoint has acquired 14 Blue Shield Blue Cross plans in 14 states.

Two days after WellPoint's purchase of WellChoice was announced, another significant merger occurred between two health insurance companies. On September 29, **HIP Health Plan of New York** and New York City-based **Group Health** disclosed that they would merge. Essentially a merger of equals, no money will change hands. However, by combining HIP's 1.4 million members with Group Health's 2.6 million members, the newly-merged firm and its 4 million members immediately becomes a regional powerhouse in the New York City area.

Both mergers change the competitive landscape in New York City.

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WellPoint did not have critical mass in this region, which is why it was interested in WellChoice. Analysts see the acquisition of WellChoice as a strategic market response by WellPoint. That's because last year, **UnitedHealth Group**, Inc. spent almost $9 billion to purchase **Oxford Health Plans** and **Mid Atlantic Medical Services**.

Defensive Response

As health insurance industry heavyweights bulk up in the northeast market, the merger of HIP and Group Health can be seen as a defensive response. Both are not-for-profit organizations. HIP has been doing its own acquisitions. In March, HIP purchased **ConnectiCare**, which has 270,000 members. Then, in June, HIP agreed to acquire **PerfectHealth Insurance Co.**, a provider of health savings accounts (HSAs).

For laboratories and pathology group practices in the greater New York City metropolitan area, consolidation of insurance companies will likely lead to lower reimbursement. The large size—and the shrinking number of competitors—gives health insurance giants like WellPoint, UnitedHealth, and HIP–Group Health greater leverage when negotiating contracts with providers.

In fact, that's the precise prediction of Kenneth Raske, President of the **Greater New York Hospital Association**. "It's economics 101: the more consolidated the marketplace becomes, the tougher the bargaining position that insurers take with providers," he said. "Our hospitals [in New York] are in economic turmoil and these mergers are only going to exacerbate the situation."

Raske is referring to the deteriorating finances of many hospitals in New York state. In 2003, hospitals in the state lost a combined $277 million. In that same year, health insurers in New York state reported total net profits of $1.5 billion.

The **American Medical Association** released public statements criticizing WellPoint's acquisition of WellChoice. The AMA points out that, between 1999 and 2005, health insurers and managed care organizations have done more than 400 mergers. During that same time, it notes that health insurance premiums have increased, but there has been no corresponding increase in benefits. In fact, the **Kaiser Family Foundation** has published data that documents a 73% increase in the average cost of health insurance premiums since 2000.

More Insurer Consolidation

It was just 15 weeks ago when THE DARK REPORT predicted that consolidation of health insurers would intensify. *(See TDR, July 11, 2005.)* At that time, we were responding to the acquisition of **PacifiCare Health Systems** by United Health Group, Inc. That deal was worth $8.5 billion. Post-merger, it makes UnitedHealth the nation's second largest health insurance company, with 26 million beneficiaries.

The acquisition of WellChoice, along with the merger of HIP and Group Health, is a speedy validation of THE DARK REPORT'S prediction. Consolidation within the health insurance industry is generally unfavorable to the long-term interests of laboratories and pathology group practices.

Concentration of market power makes it easier for health insurers to dictate coverage terms and reimbursement levels to physicians. THE DARK REPORT also believes the current round of consolidation among health insurers is partly a strategy to improve the largest payer's ability to compete in the Medicare Part D market. That's the

Medicare prescription drug benefits program that takes effect in just a few months.

Some on Wall Street concur. "This is motivated in part by the Medicare Part D plan and the fact that managed-care players will be marketing to seniors—and drug spending is an important part of Medicare Part D," declared John Farrall, an analyst at **National City Private Client Group**, who specializes in the healthcare sector.

Tougher Negotiations

The ongoing consolidation of health insurance companies is not a positive trend for the laboratory industry. Concentration of managed care contracting power amongst fewer payers in local communities allows the biggest health insurers to negotiate tough terms with physicians, hospitals, and other types of healthcare providers.

However, emerging market forces, including consumer-directed health plans, have the potential to moderate the negative influence that today's behemoth health insurers have upon provider reimbursement. In particular, strategic experts like **McKinsey & Co.** are already predicting that consumer-directed health plans will find rapid acceptance in the marketplace, by both consumers and employers.

Soon To Be Obsolete

As health savings accounts (HSAs) and similar health benefits become more popular, McKinsey believes that today's business model for health insurers will become obsolete. *(See TDR, July 15, 2005.)* One early sign of such change is **Aetna, Inc.'s** decision to post individual physician charges on its Web site and give beneficiaries access to this information. Pathologists and laboratory executives will find much on this subject in coming issues of THE DARK REPORT. TDR

AMA Slams Consolidation Of Health Insurers

EARLIER THIS YEAR, A STUDY WAS PUBLISHED by the **American Medical Association** (AMA). Titled "Fourth Edition of Competition in Health Insurance: A Comprehensive Study of U.S. Markets," it analyzed the impact of acquisitions within the health insurance industry.

The AMA is concerned about the concentration of power in regional markets by dominant health insurers. Authors of the study used the Herfindahl-Hirschman Index (HHI). This index is a component of the guidelines, used since 1997, by the **Federal Trade Commission** (FTC) and the **Department of Justice** (DOJ), when reviewing the competitive impact of mergers. When a market has an HHI index of 1,800 or higher, that market is considered "highly concentrated" by federal regulators.

In a finding termed "alarming" by the AMA, the study concluded that "for the combined HMO and PPO markets, 86 of the 92 metropolitan areas had an HHI that exceeded the federal threshold of 1,800. In addition, the study found that in 87 of the 92 markets, a single insurer had a market share of 30% or greater and that in 34 of the markets, a single insurer had a market share of 50% or greater."

In response to these findings, The AMA declared "The AMA is concerned that the United States is heading toward a commercial health insurance system dominated by a few publicly-traded companies that operate in the interest of shareholders, and not primarily in the interest of patients. It is time for the federal antitrust enforcement agencies to reexamine their enforcement priorities which have resulted in minimal scrutiny of health insurers and aggressive pursuit of physicians."

The AMA, disturbed at anti-trust actions taken against physicians in recent years, is arguing that the consolidation in the health insurance industry has already created anti-trust violations that should be investigated and acted upon by federal regulators.

OML Graduates First Distance-Learning MTs

It's the pay-off for a two-year program to recruit and train new laboratory staff

CEO SUMMARY: Faced with staffing shortages and a ready pool of B.S. graduates in the local community, two years ago, Oregon Medical Laboratories decided to use long-distance learning programs to recruit and train employees interested in earning certification as MTs and MLTs. This business strategy paid off. The first group of students has graduated and the next group is already at their studies.

TO INCREASE ITS POOL of skilled laboratory staff, **Oregon Medical Laboratories** (OML) recently graduated its first group of cyber-trained Medical Technologists (MTs) and Medical Laboratory Technicians (MLTs).

Three OML employees earned their MT certificates from the distance learning program at the **Medical College of Georgia**, located in Augusta. Another OML employee earned an MLT certificate from the distance learning program at **Weber State University** in Ogden, Utah.

Business Strategy Validated

This validates a business strategy OML initiated two years ago. Faced with an inability to recruit enough MTs and MLTs to meet staffing needs, Oregon Medical Laboratories, based in Eugene, Oregon, launched a proactive program with the twin goals of recruiting interested and qualified employees, then helping them achieve MT and MLT certification through the use of long-distance training. *(See TDR, June 16, 2003 and July 7, 2002.)*

"OML employs about 200 MTs and MLTs," stated Ran Whitehead, CEO of Oregon Med Labs. "Because the average age of our MTs is nearly 50, it won't be long before retirements further thin our ranks. We studied our staffing trends over the last five years and identified a pattern. Assuming OML maintains both its current rate of growth and its current rate of employee turnover, we project a need for ten new MTs each year. That study motivated us to get serious about proactively recruiting new employees, then helping them earn certification as MTs and MLTs.

"With the **University of Oregon** here in Eugene, there is a sizeable pool of college graduates with degrees in chemistry and biology. Many want to stay in this area, but can't find jobs. We saw an opportunity to match those people with jobs inside OML," explained Whitehead.

"Because there were no MT or MLT training programs in our area, we decided to utilize long-distance learning programs to help our new hires achieve professional certification in laboratory medicine."

"That's why our business strategy was organized around two primary goals," stated Judith McClain, OML's Education Coordinator. "One, we wanted to fill staff openings in our lab. Two, we wanted to create a better career path for existing employees and any students attracted into the distance learning program.

"We looked for accredited distance learning programs that didn't require actual 'campus time' that would be difficult for employed students," she added. "For example, I learned that Medical College of Georgia (MCG) has offered an online distance learning program for the last 12 years. The distance learning program at Weber University in Ogden requires the MT candidate to be an MLT.

Learning Via The Internet

"With distance learning, our interested employees were able to go right into MCG's MT program, leading to a second B.S. degree," McClain observed. "Even if candidates already have a B.S., we found that a second Bachelor of Science degree is appealing to most of them. Also, Medical College of Georgia is developing a long-distance Master's program. To add further appeal to enroll in a distance learning program, OML offers incentives such as tuition reimbursement and scholarship money to current employees.

"Now that we have graduated the first group of students trained via distance-learning programs, OML is expanding the program," commented McClain. "A new group of students started this fall, using our new dedicated training room. Their clinical rotation classes will be kept small and we want to start a new batch of students every year," she stated. "That means we will conduct first- and second-year programs simultaneously.

"We are quite excited about the momentum created by this program,"

Tapping Local Resources To Fund Training Efforts

ALL SORTS OF POSITIVE SYNERGIES OCCUR when laboratories join forces with their local academic institutions and workforce development agencies to develop training opportunities for Medical Technologist (MT) and Medical Laboratory Technician (MLT) certification. It is the same model that has proven effective in addressing nursing shortages.

"We partnered with Lane Workforce Partnership (LWP) to form a consortium involving other local healthcare employers," stated Judith McClain, Education Coordinator at Oregon Medical Laboratories. "Together we identified distance-learning options and coordinated the technology and infrastructure to support a program."

LWP is a private, non-profit workforce development organization that assists businesses with recruiting, training, and retaining employees. It also helps individuals find employment and advance in their careers. "Many local governments have similar initiatives," noted McClain. "Any laboratory interested in developing a distance learning program should contact their local workforce development program."

"In putting together our business model, we looked at our costs for recruitment," McClain explained. "We were able to shift some of the advertising, bonus, and orientation dollars to help fund the distance-learning program. We determined that it costs OML approximately $20,000 to replace one MT. We did not have to crunch many numbers to recognize the rapid return on investment of a distance-learning program.

"For additional funding, we turned to the consortium. OML and LWP jointly received a workforce development grant from Lane County's Economic Development Standing Committee. The purpose of the grant was to assess and train emerging and incumbent workers for entry-level jobs in medical laboratory technology and allied health careers. Our proposed distance learning program fit perfectly. OML provided clinical rotation opportunities for the students, as well as mentoring and scholarships."

observed McClain. "Its success at helping us attract quality employees has caught the attention of other laboratories across Oregon. In Medford, Oregon, **Medford Medical Center** is now using the MCG program."

Oregon Educators

The interest of OML and other labs in distance learning has been noticed by educators in Oregon. **Portland Community College** (PCC) is establishing a pilot program for MLTs in collaboration with community colleges to coordinate its course work to insure that all course pre-requisites and credits are transferable. OML, along with two other Oregon hospitals, will provide the essential clinical rotation opportunities for the students. PCC hopes to collaborate with the Medical College of Georgia, so the MLT students from PCC can seamlessly be accepted into advanced MT courses at MCG in order to obtain their Bachelors' degree in MT from the Medical College of Georgia.

"PCC wants its online distance learning program to be a resource for rural hospital labs, as well as for OML," stated McClain. "This approach is feasible for hospital labs with sufficient testing volume and a test menu broad enough to meet the clinical rotation component."

Unexpected Benefits

OML realized a number of benefits from their online distance learning program—some expected, some not. "This first class represents significant progress in meeting our staffing needs," stated McClain. "It has also contributed to a noticeable improvement in employee satisfaction.

"One unexpected benefit has been a new sense of job enhancement among existing staff as they teach and train students in clinical rotation," she noted. "Another benefit is the continued employment of a staff member here who enrolls in the program. These are employees who do their studies via a long-distance training program, do their clinical rotation requirements in our laboratory, and continue to perform job duties for OML. There's no break in employment and it's a win-win program for all stakeholders."

The success of the OML and MCG programs proves that online distance learning is a cost-effective strategy for developing a qualified laboratory workforce. As it did two years ago, THE DARK REPORT continues to predict that such programs will continue to expand across the country. If there is a drawback, it is the fact that long-distance learning programs, by design, require two or more years to produce MTs and MLTs. For that reason, laboratories interested in this approach should move expeditiously.

Grant Money Sources

Further, laboratories should explore the range of economic development grants and funding programs designed to boost employment in their community. Oregon Medical Laboratory received grant money from the county economic development agency to help fund its MT and MLT training programs. Across the country, many laboratories have tapped similar sources of money to supplement their employee recruitment and training programs.

Not surprisingly, the growing interest in long-distance learning programs is encouraging more colleges and universities to develop and offer such programs. This reflects advances in computer technology and Internet-based applications. Whether these solutions are effective in solving the long-term shortage of MTs and MLTs remains to be seen. In the meantime, however, they are useful in helping laboratories meet their staffing needs. **TDR**

Contact Judith McClain or Gloria Foust at 541-641-8029.

—by Pamela Scherer McLeod

Medi-Cal Abandons Lab Contract Scheme

Plan to contract with selected labs collapses from its own complexity

CEO SUMMARY: Another threat to limit all laboratories' access to Medicaid patients has ended. Just as the Medicaid lab contracting initiative proposed last year in Florida collapsed from its innate complexity, so also has a similar contracting initiative collapsed in California. In both cases, state Medicaid administrators resorted to a reduction in lab fees as the primary way to meet budget objectives.

IT'S THE DEATH OF ANOTHER DUMB BUREAUCRATIC IDEA that involved Medicaid contracting for laboratory testing services. California's **Department of Health Services** (DHS) has abandoned plans to enter into contracts with designated labs selected to be Medi-Cal providers.

The decision to cancel this contracting program was communicated in a public letter from DHS dated September 19, 2005. During 2004, DHS had initiated a scheme to negotiate contracts with clinical laboratories that met specific criteria. Laboratories with such contracts would be allowed to provide lab testing services to the Medi-Cal program. Laboratories without such contracts would be excluded as Medi-Cal providers. *(See TDRs, May 4, 2004 and November 22, 2004.)*

"This Medi-Cal lab contracting initiative collapsed of its own complexity," stated one lab executive who works in California. "DHS finally figured out that it was going to cost far more to administer the program than any savings that might be realized."

"This strategy is reintroduced every time the state faces a budget crisis," observed another source. "It cost labs a lot of money to respond to this application because of the extensive documentation requested. I've heard stories that some labs delivered truckloads of paper to DHS when they submitted their application as part of the contract process."

For laboratories in California, the DHS decision to drop this contract award process is welcome news. On April 5, 2004, the California DHS mailed a cover letter and RFA (Request for Application) to 500 independent laboratories. Its intention was to sign contracts with a specific number of qualifying laboratories.

Without a Medi-Cal contract, a laboratory would be excluded from doing lab tests for Medi-Cal patients. By intent, Medi-Cal program administrators were preparing to use these contracts as a way to include specific laboratories on the Medi-Cal laboratory services provider panel, while excluding all other laboratories from the state's Medicaid program.

At the same time that Medicaid officials in California were pursuing this scheme, Florida's **Agency for Health Care Administration** (AHCA) was embarked on a parallel lab services contracting scheme. However, the Florida plan was even more extreme. AHCA wanted to award a single laboratory a three-year contract to perform all outreach testing services in the state. That effort collapsed earlier this year. *(See TDR, January 3, 2005.)*

Bellwether States

For the laboratory industry, California and Florida are bellwether states. Any managed care or Medicaid lab contracting initiatives that succeed in these two states tend to be copied in other states. The Medicaid lab test contracting proposals, proposed last year in both Florida and California, represented a significant threat if they were implemented—and were then copied by states looking for remedies to their own Medicaid budget crises.

There was another disturbing element to the Medi-Cal lab contracting scheme. The intention was to sign contracts with a specific number of "qualifying" laboratories (as defined by the Medi-Cal program). Without a Medi-Cal contract, a laboratory would be excluded from doing lab tests for Medi-Cal patients.

If a laboratory holding one of these Medi-Cal contracts was ever deemed to have violated terms of the contract, it would be subject to unilateral revocation by Medi-Cal. The effect was to shift the burden of proof to the lab to show it had not violated the terms of the contract.

Medi-Cal officials believed the contracts would accomplish two primary goals. First, the negotiated contract price would be reduced from existing Medi-Cal fees, saving money for the program. Second, Medi-Cal would only contract with laboratories that it viewed as being fully compliant with all laws and regulations. Because fraudulent billing of the Medi-Cal program is an ongoing problem, Medi-Cal officials believed the contracting process would make it possible to exclude any laboratories it suspected might be capable of fraud.

Of course, such an approach is contrary to the established concepts of "any willing provider" and "due process of law." Also, such contracting schemes raise another issue: whether the process of selecting a winning laboratory was free of bias and free from manipulation, either by bureaucrats or by laboratories. TDR

—by Pamela Scherer McLeod

Lab Cost Study Ongoing In British Columbia

EVEN AS MEDICAID PROGRAMS in California and Florida were announcing complex laboratory contracting proposals, government health administrators in British Columbia were putting forth their "Lab Reform" plan, which included fee cuts and competitive bidding.

Canada's Supreme Court ruled the plan was illegal. The **British Columbia Medical Association** and the government then worked out an interim one-year agreement. Laboratories agreed to accept a 20% reduction in reimbursement while an investigative task force was established to explore ways to reduce the cost of laboratory testing. *(See TDR, November 22, 2004.)*

"The laboratory fee review panel is reviewing actual cost data to come up with a weighted average, which factors in overhead," stated Douglas Buchanan, CEO and Managing Director of **BC Biomedical Laboratories, Inc.**, based in Surrey, British Columbia. "A panel on pathology workloads is using global benchmarks on productivity to establish a new model there. There have been no legislative changes and no milestones reached, yet. We expect to see those crystallize over the next six months."

NYC Collects Lab Results To Monitor Diabetics

127 labs in the city will report HbA1c test results electronically

CEO SUMMARY: With an estimated 780,000 diagnosed and undiagnosed diabetics in their city, officials at the New York City Department of Health and Mental Hygiene decided to take proactive action. Labs will now electronically report HbA1c test results electronically to city health officials, who will use this information to proactively interact with both clinicians and patients to improve diabetes care and outcomes.

IT'S A DOUBLE-EDGED SWORD when Big Brother decides to put private laboratory test results to use for "public good." Two recent government healthcare initiatives indicate a shift in the country's healthcare system from a reactive to a proactive paradigm.

At the heart of this change is a government effort to use lab testing and test data to change patient outcomes. This move is significant to laboratory administrators and pathologists because it is a tangible sign that some part of the healthcare establishment recognizes that more effective use of laboratory testing has the potential to significantly improve healthcare outcomes.

Using Lab Test Data

The boldest initiative has been launched by the **New York City Department of Health and Mental Hygiene** (DHMH). It is taking the first steps to create a diabetes patient registry that will be used to identify and manage the treatment of diabetic patients. A key part of this effort is for laboratories to report patient lab test data to the registry.

New York considers diabetes to be its single biggest health problem. Living in the city are 530,000 diabetics. Another 250,000 people are believed to be undiagnosed diabetics. Diabetes is the fourth leading cause of death in New York City. In 2003, 1,891 people died of the disease and it is now costing $7 billion to treat diabetics in the city.

In a public health agency first, DHMH is requiring 127 laboratories in the city to electronically report HbA1c results into the Electronic Clinical Laboratory Reporting System (ECLRS), run by New York state. When a patient's hemoglobin A1c results are 8 or higher, DHMS employees plan to alert that patient's physician. They can also send an alert letter to the patient.

DHMS will not have patient consent to collect this data. It says that access to the data base will be under tight control. It also intends to allow patients to opt out of the project.

Several aspects of the project trouble consumer advocates and privacy experts. "This isn't smallpox," declared

James Pyle, an attorney actively representing health privacy groups. "The state, or the city in this case, does not have a compelling interest in the health of an individual that overrides that individual's right to privacy."

The counter to this argument is that diabetes needs to be handled in the same fashion as public health threats. "We respond with surveillance when we believe something has reached epidemic proportions," observed Amy Fairchild, Ph.D., a professor in the School of Public Health at **Columbia University** in New York City, "and this may fit the profile. Have we become a nation of obese people who are all going to get diabetes?"

Public Health Sector

Regardless of the ethical arguments for and against the NYC effort to proactively intervene in diabetic care, the reality of this program should catch the attention of pathologists and lab managers everywhere. It is an early marker of how the public health sector has a motive—and the power—to act assertively on issues it deems relevant to protecting public health.

It is also a demonstration of how laboratory test information is growing in value for health policy makers. By collecting this data across a population, policy makers recognize they have the opportunity to in-tervene with clinicians and patients. How-ever, this puts the lab industry squarely in the middle of a debate over the right to privacy versus the "public good."

As the country moves ever closer to an integrated national health information system, opportunities for government to use private healthcare data for "legitimate" public health purposes—such as in the case of the New York City proposal—will soar. And so will the opportunities for government to infringe on the individual's right to keep that information private.

NYC Borrowing Strategy Now Used In New Zealand

THROUGHOUT THE WORLD, there are multiple examples of using lab test data to monitor diabetic patients.

One of the most interesting examples comes from New Zealand. In Auckland, the **Counties Manukau District Health Board** serves 400,000 people. This region includes a large Maori and Pacific Islander population, which has a high incidence of diabetes.

It initiated a program to electronically collect hemoglobin A1c lab test results, then track and manage diabetic patients. The system has built-in best practice rules. Based on test results and other information about a specific patient, the system, called the Integrated Care Server, will send treatment recommendations to the attending physician.

This automated system has made a big contribution to diabetes care. The Manukau Health Board reports that the number of diabetic patients with an hemoglobin A1c result of 9 or higher was reduced from 34% to 7% since implementation of the automated system.

The New York City diabetes monitoring project is a significant event. It pushes the lab industry one step deeper into a new debate over the ownership of, access to, and uses for laboratory test data.

What Kind Of Response?

Individual laboratories and pathology groups can expect to see more of these types of initiatives, particularly from Medicare and Medicaid. What adds to the challenge is the fact that the laboratory industry, collectively, has yet to formulate either a policy or a response to this new dimension of healthcare. For that reason, lab managers and pathologists will need to devise their own strategy on this issue. **TDR**

—by Pamela Scherer McLeod

Lab Industry Briefs

LAB TESTS IN PHARMACIES ARE NOW A REALITY IN MANCHESTER, ENGLAND

IT IS OFTEN SUGGESTED that pharmacies are a logical place to combine laboratory testing with prescription services. Such an arrangement would be consumer-friendly and has the potential to improve patient care while lowering costs.

In Great Britain, the National Health Service has launched a pilot program to test this concept. Earlier this year, it began remodeling 22 pharmacies to accommodate laboratory testing. Four primary care trusts in Manchester, England were selected to participate in the program. The pharmacies are located in the vicinity of these primary care clinics. Remodeling in the first four pharmacies was expected to be done this summer, with lab testing services to start shortly thereafter.

Based in pharmacies, the diagnostic services will be clinical management and point-of-care testing (POCT) for diabetes (including HbA1c), cardiovascular disease (including cholesterol, HDL-cholesterol), and anticoagulation (including INR).

The pilot project will require information technology support. In the first phase, a communication capability will be established to link the 22 pharmacies with primary care clinics and secondary care pathology laboratories. (In the United Kingdom, the term "pathology" encompasses both clinical laboratory and anatomic pathology services.)

There will also be an information technology solution developed to capture the POCT results generated in the pharmacy, along with outcomes of the clinical consultations, and performance management data.

The performance management data is important and relates to the speed with which patients are served. A major issue in the United Kingdom is the time required for patients to access healthcare services. Consumers have made their unhappiness about long wait times known to politicians.

That is why one primary objective of putting laboratory testing into pharmacies is to reduce the time required for patients to provide laboratory test specimens, get the test results, and receive prescriptions.

In the United States, only a limited number of situations are known where a pharmacy offered laboratory testing. However, in recent years, pharmacists in several states have pushed for legislation to expand their scope of practice to include laboratory testing.

NEW PHARMACOGENOMIC ASSAY LAUNCHED BY GENZYME CORP.

PHARMACOGENOMICS IS BEING PUSHED another step forward by **Genzyme Corporation**, which announced last week that it was offering a genetic test to help physicians predict which patients will respond better to specific cancer drugs.

Genzyme's EGFR Mutation Assay "will help to identify patients likely to respond to therapies targeted for the treatment of non-small cell lung cancer (NSCLC)...EGFR mutations have been shown to correlate with clinical response to certain drugs, including Tarceva® (erlotinib) and IRESSA® (gefitinib), used in treating this deadly form of cancer."

Genzyme's actions are sure to intensify the debate over personalized medicine. Genzyme has not submitted its new lab tests to the FDA for approval and no drug manufacturer has yet endorsed the use of Genzyme's tests in conjunction with its drug.

Genzyme licensed rights to the test, which is based on research done at the **Dana-Farber Cancer Institute** and **Massachusetts General Hospital** in Boston, Massachusetts. However, other researchers, including Fred Hirsch at the **University of Colorado Cancer Center**, are expected to produce commercial laboratory tests based on their work with the EGFR gene.

Genzyme's new test demonstrates that the time from research to clinical test continues to shorten. Further, it seems Genzyme chose to bring this test to market as soon as possible to beat other companies preparing similar types of diagnostic tests. That is further confirmation that the development and introduction cycle for new molecular assays is growing shorter and shorter.

BIG KANSAS CITY FIRMS PROPOSE MAJOR HEALTH INFO NETWORK

MAJOR EMPLOYERS IN KANSAS CITY are taking a proactive role in developing a Regional Health Information Organization (RHIO). The goal is to create an electronic community health record.

The initiative is called "Healthe." Among the 12 private sector employers participating are **Cerner Corp.**, **Children's Mercy Hospitals and Clinics**, and **Truman Medical Centers**. The project is in the talking stage, with no set timetable for implementation.

Organizers are discussing an RHIO informatics platform that would include claims data, prescription data, patient demographics, allergies, and laboratory test data. Employers hope this initiative would accelerate adoption of electronic medical records (EMRs) by physicians in the Kansas City area. As currently proposed, an independent, not-for-profit organization would be created to develop and manage the Healthe project.

The initiative in Kansas City to create a regional health informatics platform is not unusual. Similar efforts to create RHIOs are underway in communities throughout the United States. This market development reinforces the need for all laboratories and pathology group practices to have an effective strategy for enhancing information-based services and capabilities.

HURRICANE KATRINA TESTS HOSPITAL EMR SYSTEMS

IN THE WEEKS FOLLOWING Hurricane Katrina, news has slowly emerged about how hospitals with EMR systems maintained clinical services and access to essential patient records.

On the Mississippi Gulf Coast, the two-hospital **Singing River Hospital System** operates an EMR system installed in 2003. The hospitals are linked by two independently-routed fiber optic lines, configured into a SONET ring. When the hospital closest to the Gulf was hammered by the storm, full access to patient records was maintained. Only when the power supply failed on two occasions, did hospital staff need to use paper forms.

In New Orleans, the **Veterans Administration** hospital was evacuated after the first floor flooded. Back-up tapes of the VISTA system had been prepared on Friday, before the storm, and Monday, before the levees broke. These tapes were flown to Houston. Programmers wrote a special program and within a few days, information on the VA patients from New Orleans was available to VA clinicians anywhere. TDR

Health Technology Update

Cervical Cancer Vaccine Trial Generates Huge Headlines

Because of its potential to prevent cancer, HPV vaccine is closely-watched by media

THIS IS AN UPDATE ABOUT THE RACE to be first to market a vaccine to prevent cervical cancer. **Merck & Co.** is currently in the lead.

On October 6, 2005, Merck released results of a trial that is part of a phase III study of its vaccine, called GARDASIL™ (a "quadrivalent human papillomavirus types 6, 11, 16, 18, recombinant vaccine"). In the trial, the vaccine prevented 100% of high-grade cervical pre-cancers and non-invasive cervical cancers.

Approximately 12,000 women from 13 countries participated in this trial. A total of 25,000 women from 33 countries are involved in the full phase III study. Details of the study were widely publicized and are easy to find on the Internet.

Merck expects other trials in the phase III study to be completed shortly. It plans to apply, by year's end, to the **Food & Drug Administration** (FDA) for approval to market the vaccine. Under a "best case" timeline, Merck indicates that the HPV vaccine could be sold in the United States during 2006.

Merck's major competitor in the race to produce an HPV vaccine is **GlaxoSmithKline** (GSK). Its phase III study has enrolled 35,000 women in 14 countries and is ready to commence. GSK's vaccine is called Cervarix and it expects to apply for approval in Europe by the end of 2006.

THE DARK REPORT considers the effort to develop a cancer-preventing vaccine to be significant, for several reasons. First, it demonstrates a practical application of molecular technologies to a healthcare problem. In the process, clinical acceptance of this vaccine will eventually alter, in radical ways, the cervical cancer screening protocols that currently apply to every woman in the United States.

Next Round Of Vaccines

Second, few people know about the next wave of vaccines planned to follow introduction of the HPV vaccine into clinical use. At GlaxoSmithKline alone, there are plans to launch five new vaccines over the next five years. These include vaccines for rotavirus gastroenteritis, pneumococcal disease, a new flu vaccine, and new vaccine combinations against meningitis. Glaxo is telling financial analysts that, by 2010, the world market for these types of vaccines will total between $11 billion and $18 billion.

Third, it is important to remember that clinical applications of these molecular technologies will soon multiply exponentially. This raises interesting questions about how diagnostics will change in response to vaccines which prevent disease—and reduce or eliminate the need to perform lab tests for screening and diagnosis of those diseases. TDR

Canadian Lab Confab Reveals Useful Insights

In this single-payer health system laboratories face similar challenges

***CEO SUMMARY:** Last month, a group of Canadian early-adopter pathologists and laboratory directors came together for the first-ever* **Executive Edge** *forum to share best practices and other cutting-edge developments in laboratory management. Among the noteworthy developments is Canada Health Infoway, a national effort to create a universal electronic health record as early as 2009.*

LABORATORY PROFESSIONALS from across Canada and the United States convened in Toronto last month at the first-ever *Executive Edge* forum on laboratory management with a focus on issues of special interest to Canadian laboratories.

"Like their peers south of the border, Canadian laboratories are battling inadequate funding against a steady increase in demand for lab services and an ever-growing shortage of trained technical staff," observed Sheila Woodcock, President of **QSE Consulting** of Toronto, Ontario and a co-producer of *Executive Edge*. "At the same time, several provinces are initiating laboratory accreditation guidelines based on ISO standards and encouraging laboratories to adopt quality management tools like Lean and Six Sigma."

Early-adopter laboratories in British Columbia in the West and Nova Scotia in the East shared their successes and setbacks at *Executive Edge*. In fact, **Providence Health Care** (PHC) of Vancouver, British Columbia was one of the first laboratories in Canada to use Lean methods to redesign its high-volume core chemistry and hematology laboratory.

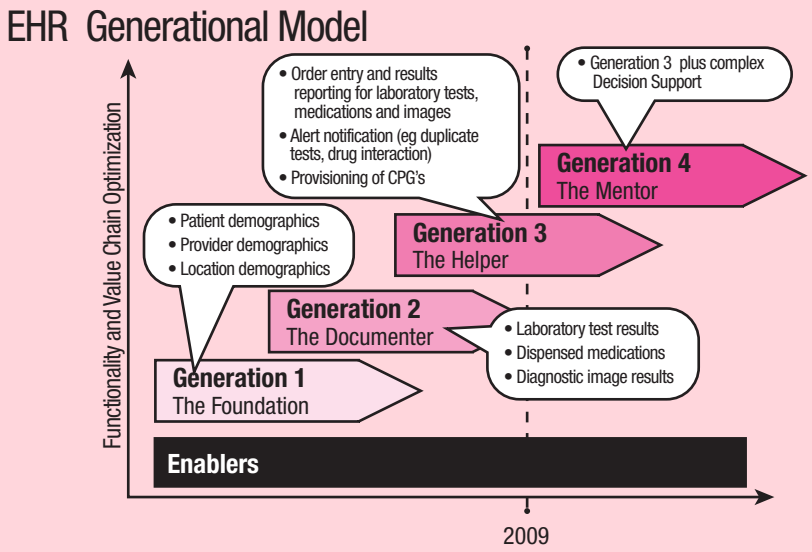
"Facing the pressures to improve patient outcomes, to do more with less money and resources, and streamline work processes in our laboratory, we decided to use Lean techniques," stated Enid Edwards, M.D., Medical Director at PHC. "We recognized the need to engage operations experts that could help us rethink our traditional paradigm of laboratory operations.

Used Outside Expertise

"For that outside support, we turned to **Ortho-Clinical Diagnostics**," she said. "Using Lean, Six Sigma and Design Excellence principles, we slashed our test turnaround time by 40% and reduced operating costs by as much as 50%. Benefits extended beyond those improvement measures. What resulted was the unexpected opportunity for our laboratory—and its pathologists—to regain a higher profile within our health system."

Edwards is referring to efforts in British Columbia to improve patient outcomes. "Providers, including labora-

Infoway's "Grand Plan" for an Integrated Informatics Platform to Serve Healthcare



This table was presented at the *Executive Edge* forum in Toronto, Ontario last month. It shows how Canada Health Infoway plans to move, in four generations of product introduction, from the current state to a national, integrated healthcare informatics system. Laboratory test results will be introduced in Generation 2. Generation 4 is planned to be the complete electronic health record (EHR), combined with a sophisticated clinical decision support system.

tories, will increasingly be ranked and reimbursed according to performance measures," stated Jane Crosby, R.T., Laboratory Leader at PHC. "Our Lean project is a deliberate strategy to put our laboratory ahead of that curve."

Nova Scotia Lab Goes Lean

On Canada's East Coast, the laboratory at **IWK Health Centre** in Halifax, Nova Scotia is using Lean and Six Sigma methods to revamp lab operations in different departments, using an incremental approach. One major benefit has been streamlined specimen flow through the laboratory, along with more consistency in the output of individual work processes.

"In the laboratory, our Lean environment allows med techs to become like a chef who focuses on preparing the meal without the distraction of having to chase down the lettuce and tomato and meat slicer before each step," stated Kent Dooley, Ph.D., Director of Pathology and Laboratory Medicine, IWK Health Centre. "Staff spends more time on the value-added steps and less time searching for items or prepping for the next batch."

Integrated Informatics

Canada seems to be moving faster than the United States on creating an integrated informatics platform to support the healthcare system. Even as the United States is moving forward to develop the proposed National Healthcare Informatics Infrastructure, a parallel effort is under way in

Canada. Canada Health Infoway was launched as an independent, not-for-profit corporation. It is chartered to develop an electronic information system for patients that reaches across all the Canadian provinces and territories.

Infoway's role is to be a strategic investor and catalyst with these governments, helping them develop enhanced healthcare informatics solutions. It is an ambitious plan, and requires establishing information systems in therapeutic drugs, laboratory, diagnostic imaging, public health, and telemedicine. A major portion of Infoway's investments will be to create an electronic health record solution and a "Client, Provider, Location" registry.

Implementation Timetable

Infoway's timelines are tight. By 2009, Infoway wants to have its third-generation laboratory information solution deployed. *(See sidebar on page 16.)* Five provinces are already in Generation 1 implementation of the laboratory information solution. These provinces represent about 60% of Canada's total population of 30 million.

If Infoway is successful at meeting these timetables, Canada is likely to be among the first developed countries in the world to deploy an integrated healthcare information system that functions at a national level. The closest informatics initiative to be found in the United States currently is at the **Veterans Administration**. It has created a regional, paperless, EHR (electronic health record) system. However, it is encountering significant obstacles in its efforts to link the regional EHRs into a uniform national system.

Another interesting insight was delivered by Bruce Friedman, M.D., Professor of Pathology at the **University of Michigan Medical School** of Ann Arbor, Michigan. Friedman spoke on the subject of laboratory information systems and the emerging dominance of "middleware" as an important component of the informatics solution for many laboratories.

Because of the importance of informatics in today's healthcare system, along with the explosion of testing done outside the core laboratory, Friedman now defines a laboratory as "one person plus an instrument."

"My point for defining a lab in this way is this. What is of ultimate value to the healthcare system is the information produced by the laboratory test," he explained. "Anywhere that laboratory test data is produced can be considered a laboratory—and the key management objective is to get that lab test data into a clinical repository and report those results, in real time, to the clinicians. This definition eliminates the size of the laboratory as a critical factor and emphasizes the value of all lab data for an individual's longitudinal health record.

"We also need to break down the 'glass wall' standing between laboratory professionals and clinicians. To do this, we have to transport ourselves to the 'sweet spot'—which is the moment in time and space when the clinician needs to decide which lab test to order to develop a diagnosis, and, upon receiving lab test results, what type of therapy is appropriate for the patient," said Friedman. "Laboratories need to be at that 'sweet spot' helping the clinician at those moments of decision. By using the right information technology, laboratories can be the clinical knowledge resource for clinicians, regardless of their location, because information technology destroys time and distance."

For more details on *Executive Edge*, visit *www.exec-edge.net*. TDR *Contact Sheila Woodcock at 902-766-4295.*

—Pamela Scherer McLeod

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

XIFIN, Inc. has been recognized as one of San Diego's "Technology Fast 50" companies. XIFIN, based in San Diego, provides laboratories and hospital outreach programs with a Web-based software system for managing laboratory accounts receivables and financial operations. To make this list, compiled by **Deloitt and Touche, LLP**, a company must have had revenues of at least $50,000 in 2000 and $1 million in 2004, generated from proprietary technology that is the source of "a significant portion of the company's operating revenues."

VIROLOGIC'S NEW NAME

There's a name change in the IVD world. **ViroLogic, Inc.** has changed its name to **Monogram Biosciences, Inc.** Based in South San Francisco, California, the company is best known in the laboratory industry for its menu of assays that help identify drug resistance in HIV patients.

PATHOLOGIST WINS NOBEL PRIZE IN MEDICINE

This year's Nobel Prize for physiology and medicine was awarded to J. Robin Warren, M.D., a pathologist, and Barry J. Marshall, M.D., for their discovery of *Helicobactor pylori* bacteria and its role in causing ulcers. Both were working at the **Royal Perth Hospital** in Perth, Australia at the time this research was conducted. In press coverage of this Nobel prize, most stories focused on the role of Marshall. That's because Marshall, a young clinical fellow at the time of this research, actually swallowed a glass full of the bacteria to demonstrate, on himself, that this bacteria could cause ulcers.

ADD TO: *Nobel Prize*

However, it was pathologist Warren who first observed that ulcers could be caused by bacteria. As described in the Nobel Award, "he observed small curved bacteria colonising the lower part of the stomach in about 50% of [ulcer] patients from which biopsies had been taken. He made the crucial observation that signs of inflammation were always present in the gastric mucosa close to where the bacteria were seen." Based on this observation, Warren and Marshall initiated a study of biopsies from 100 patients. Marshall was able to cultivate a then-unknown species of bacteria—now called *H. pylori*, from some of these biopsy specimens.

LAB CEOs FOUND IN SPICEWOOD

It seems Spicewood, Texas is becoming attractive among the lab industry cognoscenti. Recently, THE DARK REPORT walked into a local BBQ emporium for lunch. Sitting at the next table was a former CEO and his Chief Science Officer from a national laboratory, relaxing after a morning round of golf. The next evening, THE DARK REPORT was invited to help an IVD company CEO celebrate her birthday at Poodies', the famed honky-tonk owned and operated by Willie Nelson's long-time road manager. Even as a small community, Spicewood seems to be achieving a higher profile as a lab industry "must visit" locale.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 14, 2005.

UPCOMING...

- ***Private Pathology Group Practices: Are They Healthcare's Dinosaurs...and Heading to Extinction?***
- ***Middleware versus Full LIS Upgrade: Why the Laboratory Marketplace has Already Picked the Winner.***
- ***Big Changes Ahead in Laboratory Contracting for Managed Care Contracts: What Every Lab Needs to Know.***

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