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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R Lewis Dark

Founder & Publisher

New Blood and Old Issues

IT'S YET TO MAKE A FLOURISH, but **American Esoteric Laboratories, Inc.** is now funded, open for business, and has $70 million to use in pursuing its business goals. Even as this new laboratory company makes its debut, an old issue continues to gnaw at the laboratory industry: competitive bidding.

Medicare continues to move towards its latest attempt to launch a competitive bidding project for Part B laboratory testing services. Meanwhile, Florida's Medicaid program has issued an RFP intended to award a single laboratory exclusive rights to perform all non-hospital lab testing done statewide for Medicaid patients for three years. *(See pages 8-9.)*

Add to the Medicare and Florida Medicaid examples another instance of competitive bidding. This time it's the British Columbia healthcare agency. It turned to competitive bidding for laboratory testing as a way to reduce expenses. *(See pages 10-12.)* Taken together, the Medicare, Florida Medicaid, and British Columbia examples provide strong evidence that the laboratory industry has a big fight on its hands if it wants to oppose competitive bidding.

I predict this concept will continue to pop up. With demand for healthcare services and costs increasing at double-digit rates, competitive bidding will become an even more attractive option for the administrators of government health programs. One could say that momentum and inertia are on their side. Momentum comes from ever-increasing pressures to control costs and make limited budgets cover more beneficiaries. Inertia comes from the lack of creativity and the institutional barriers to innovation. From the government's perspective, competitive bidding is the path of least resistance.

The creation of a new laboratory company even as the spectre of competitive bidding comes closer to reality makes an undeniable contrast—and provides an opportunity to make a point. American Esoteric Laboratories represents new blood coming into our industry. It has ideas, energy, and capital. Whether it succeeds or fails, it will stimulate competing laboratories to improve their services and their capabilities. Everyone will benefit. In contrast, bureaucrats at these government health programs lack that same type of competitive pressure that encourages innovation and improvement. The result is more of the same, whether it really works or not. Unfortunately, competitive bidding falls in that category—and won't disappear. TDR

New Esoteric Lab Firm Does Two Acquisitions

American Esoteric Laboratories, Inc. has plenty of cash and ambitious plans

CEO SUMMARY: Armed with $70 million, American Esoteric Laboratories (AEL) wants to build a national laboratory that offers a full menu of esoteric tests. It is building a primary laboratory in Dallas, which has one of the nation's best air transport hubs. ThromboCare Laboratories and Viral Diagnostics, both based in the Dallas area, are just the first of several acquisitions planned by the nation's newest lab company.

TWO VETERAN LAB ENTREPRENEURS announced the birth of the nation's newest laboratory company on April 6, 2004.

The new enterprise is **American Esoteric Laboratories, Inc.** (AEL). It has already acquired two specialty testing laboratories in the Dallas, Texas area and is building a new laboratory facility in the Dallas suburb of Las Colinas.

"AEL was founded to provide esoteric testing to hospitals and specialty physicians," stated Brian Carr, Chairman and CEO of the new lab company. "We think there is room in the marketplace for a laboratory that offers a broad menu of esoteric tests, a discernably high level of service. and a commitment to support, rather than work against, a hospital's laboratory outreach efforts. We want to build this company from a blueprint created by customers—incorporating exactly what they want (and don't want) in a reference laboratory partner."

Those are ambitious words, since AEL is still a fledgling business. However, certain attributes of AEL give it the potential to become a tough competitor. One attribute is ample cash upon which to build the business. Another attribute is its veteran management team, which has experience, credibility, and lots of industry connections.

If cash is king, then AEL has plenty of it. It received $70 million in funding from **ABS Capital Partners** and **Oak Investment Partners**, two respected, billion-dollar investment companies.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

The management team at AEL includes some names known to longtime clients and readers of THE DARK REPORT. Chairman and CEO Brian Carr was a founder of **Pathology Consultants of America, Inc.** (PCA). This pathology physician practice management (PPM) company evolved into an owner of pathology labs under the name **InformDX**. It was acquired by **AmeriPath, Inc.** in 2002. *(See TDR, November 13, 2000.)*

Executive Team

AEL's President and COO is Jim Billington. Billington was also a key executive at PCA, InformDX, and AmeriPath. Rounding out the initial team is William Sledge, Ph.D., Vice President of Operations and Mark Farrington, Chief Information Officer. All four of these individuals have a common history at **Allied Clinical Laboratories** and its acquiror, National Health Laboratories.

AEL did not waste any time putting its $70 million war chest to work. It recently acquired **ThromboCare Laboratories** and **Viral Diagnostics**. "ThromboCare specializes in coagulation testing and Viral Diagnostics offers virology and infectious disease testing," noted Billington.

"It's not a coincidence that both laboratories are located in the Dallas-Fort Worth Metroplex," he added. "It has a great air transport hub for national operations. That is one reason we are building a laboratory here. Also, we have existing business relationships with a number of respected hospitals in Texas."

"Our target markets are hospitals and specialty physicians," explained Carr. "We want to differentiate ourselves in several ways. First, our core competency will emphasize esoteric tests which have high clinical utility and generally require a more intense support relationship between the referring clinician and the laboratory's technical staff. We don't plan to do any material amount of routine testing, and in fact, see that as a conflict in our mission."

"Furthermore, we believe the growth of molecular diagnostics and the development of new technologies in esoteric testing will increase the need for clinicians to interact more actively with their laboratory professionals," he added.

"Second, we believe 'top quality service' is a term often used by labs, but seldom recognized by hospitals and physicians. That is AEL's opportunity. If we can excel at the simple things that affect the daily life of our clients, like logistics and customer service, that will differentiate AEL in a way that hospitals and physicians will notice," Carr said.

Informatics As Trump Card

"Third, everyone recognizes that laboratories must become increasingly competent in informatics capabilities," noted Carr. "Our goal is to develop information management systems which give us the ability to seamlessly link AEL, hospital laboratories and physicians' offices."

"There is a reason we think we can be better than competing labs in this area," interjected Billington. "That's because we get to build our information systems from scratch, using current and next-generation technology. Unlike other labs which must deal with the legacies of MUMPS and other archaic technologies, AEL is building its platforms with customized, 'off the shelf' software modules designed to interact efficiently with the Internet, as well as interface with the wide range of software systems found in hospitals and physicians' offices."

Billington noted that AEL is developing informatics solutions to support

three IT strategies. "First, all of our in-house functions will be on a common platform for testing and billing," he explained. "We don't know of any laboratory which does this well and most labs struggle to move data between systems like LIS, billing, data storage and ultimately to the customer.

Outreach Software Solution

"Second, we are cultivating an outreach software package that would allow specialty physicians to use a single portal to order routine tests and access results from their local hospital outreach laboratory and order esoteric tests and access those results from AEL.

"The third IT strategy involves our internal capability to warehouse data and access it for management and customer service needs. The system we are developing will tie together lab test results, billing and collection data, and operational performance data. We will be able to manage the business accurately and in real time to deliver a measurably higher level of service to our clients."

National GPO Contracts

If AEL is to succeed on a national level, it must address the issue of GPO (group purchasing organization) contracts. "Our goal is to offer esoteric testing services services through a 'superior service channel' that already exists today," stated Carr. "That is already the bread-and-butter business of ThromboCare and Viral Diagnostics.

"When the referring hospital laboratory or referring specialist has a tough case or needs a fast answer, these cases come to ThromboCare and Viral Diagnostics regardless of GPO or managed care contracts. Differentiated quality and patient care issues drive the need for special expertise or a reliably fast answer," he explained.

"That's the type of market niche AEL is developing capabilities to serve," added Billington. "It's our bridge to build the business. As our test menu broadens and we develop our service network, we expect to win our share of GPO and managed care contracts."

During the next six months, AEL will be concentrating on some basic organizational goals. First, it must finish construction of its new laboratory facility in Dallas, currently scheduled

It's an Allied Labs Reunion Centered Around Dallas

DALLAS, TEXAS WILL BE American Esoteric Laboratories' (AEL) primary laboratory site for an interesting reason. Its current management team ran a national laboratory there more than ten years ago.

Before Allied Clinical Laboratories was acquired by **National Health Laboratories** (now **Laboratory Corporation of America**) in 1994, its national reference and esoteric laboratory was located in Dallas. At that time, the lab's General Manager was Brian Carr. The Director of Finance was Jim Billington. But there's more! Mark Farrington ran Allied's corporate informatics department. Then, upon the acquisition of Allied by National Health Laboratories (NHL), William Sledge, PhD., became technical director of the operation.

"All four of us worked together in the Dallas laboratories of Allied (later NHL)," observed Carr. "Because those labs received specimens from a national network of labs, we are familiar with the Dallas air hub and all the logistical issues of Dallas from a nation-wide service perspective. We also know many of the folks still running laboratories in hospitals throughout Texas. So it is a logical place for us to launch AEL.

"Because of these professional relationships in the region, our initial strategy is to focus building our business in Dallas/Fort Worth and the rest of the Southwest," he said. "Both Thrombocare and Viral Diagnostics have good clients in this same market. That gives us the opportunity to cross-sell existing clients of each lab."

Looking at Reference Testing Market Share

HOW BIG IS THE NATIONAL MARKET for reference and esoteric testing? Executives at American Esoteric Laboratories (AEL) were willing to share some of their analysis with THE DARK REPORT and its readers.

"In assessing the existing market, we used several methods. Each brought us close to a similar number," stated Jim Billington, President and COO of AEL. "We accept $36 billion per year as the cumulative value of diagnostic testing done in the United States. Hospital inpatient testing accounts for roughly half that number, or $18 billion.

"We believe that a good estimate of what hospitals and office-based physicians refer out as esoteric testing is between $3 billion and $4 billion per year," he continued. "Between them, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** probably do 50% of this type of testing. The balance of this testing is done by **ARUP**, **Specialty Labs**, **Esoterix**, **Mayo**, academic centers, and smaller, specialty niche laboratories.

"What is important about this reference and esoteric testing market segment, however, is not its size today," observed Billington. "It's the rate at which it is growing. Because growth rates are in double digits, reference and esoteric testing will comprise a larger proportion of all diagnostic testing than it has in past years."

for October. Second, it must then consolidate its two existing acquisitions into the new laboratory. Third, it must acquire the additional instruments and personnel necessary to give it a broad esoteric test menu. Fourth, it must finish development and installation of its customized information software systems. That may take extra time, because software developers are notoriously optimistic in their completion deadlines.

AEL's acquisition strategy is to seek niche esoteric labs, not just in Texas, but in all parts of the United States. "With one primary laboratory in Dallas, we anticipate developing 'special esoteric centers' in other locations around the country," explained Carr. "That will be based on where high quality laboratories have already built their business base. These operations will operate under one laboratory information and billing system."

Impact On Marketplace

Because of this strategy, THE DARK REPORT believes that AEL will have a slightly different impact on the lab marketplace than most would assume. It wants to buy niche labs doing specialty testing. This strategy has been followed by a number of lab companies in recent years, including **Specialty Laboratories**, **DIANON Systems**, and **IMPATH**, among others.

Each of these lab companies has acquired specialty labs doing just a few million dollars per year in sales. They bought niche labs with a solid base of clients and demonstrated expertise in a segment of esoteric testing that was positioned for growth.

In fact, specialty testing labs may be to this healthcare market cycle what the pathologist-owned, local independent laboratories were to the last healthcare cycle. During that cycle, public lab companies gobbled up independent laboratories as a primary way to grow.

In this cycle, it seems most start-up laboratories are organized around the skills and clinical interest of a physician or laboratory scientist specializing in one area of esoteric diagnostics. Once these entrepreneurs build annual revenues above two or three million dollars, they become attractive acquisition candidates. TDR

Contact Brian Carr at 615-627-3252 and Jim Billington at 972-702-6247.

Growing Criticism Hits Maryland Gen. Hosp. Lab

Public responds to results of inspections of troubled hospital laboratory in Baltimore

CEO SUMMARY: "Like peeling back layers of rotten fruit, the deeper state and federal inspectors looked into the management of the hospital's lab, the more problems they found."–Editorial,* Baltimore Sun*, April 7, 2004. Public response to the inspection report of the Maryland General Hospital laboratory has triggered criticism of how providers and accrediting agencies like JCAHO and CAP inter-relate.

AS THIS SCANDAL UNFOLDS, there is growing criticism of those responsible for failures in HIV and HCV testing at **Maryland General Hospital's** (MGH) laboratory. Inspections by healthcare accrediting agencies are also now coming under public scrutiny.

"Hospital lab had received highest rating" was the headline in the *Baltimore Sun* on April 10, 2004. Reporter Walter F. Roche, Jr. wrote "The nation's primary laboratory accreditation agency gave its highest rating to Maryland General Hospital's lab in July [2003], failing to detect serious, long-term problems that went unaddressed until a whistleblower's complaint brought in state inspectors this year."

"Accredited With Distinction"

The **Baltimore Sun** then quoted one accrediting agency's evaluation of the MGH laboratory: "'Accredited with Distinction,' the **College of American Pathologists** [CAP] reported July 16, based on a review conducted in April last year."

Criticism of the laboratory and healthcare accrediting process is one of the more interesting consequences of the problems recently uncovered in the laboratory at MGH. As disclosed earlier by THE DARK REPORT, for a 14-month period, the laboratory had reported questionable results on HIV and HCV tests to several thousand patients. *(See TDR, April 5, 2004.)*

The situation was not discovered until Kristin Turner, a former medical technologist at the laboratory, turned whistleblower. In December 2003, after getting no response from hospital administration to letters she sent pointing out problems in the laboratory, Turner then notified state health officials of her concerns.

Turner is the med tech who now tests positive for both HIV and HCV. She claims a malfunctioning lab instrument and management failures were responsible for the lab accident which exposed her to both viruses. She filed a $30 million lawsuit against the laboratory director, the hospital, and **Adaltis**, manufacturer of the instrument at issue.

Alerted by Turner's letter, state health officials inspected the laboratory in January. That led to another inspection of the laboratory on March 16, 2004 by officials from the **Centers for Medicare and Medicaid Services** (CMS), the Maryland **Department of Health** (DOH), and the **Joint Commission on the Accreditation of Healthcare Organizations** (JCAHO).

Public Reaction To Results

Earlier this month, the results of these inspections were made public. Negative reaction was strong. State Health Secretary Nelson J. Sabatini declared that the Maryland General case "shows the inadequacy of the whole process" by which accreditation of healthcare providers is done by private organizations closely involved with the healthcare providers they inspect. "We have a totally ineffective process to make sure problems are corrected or people are put out of business," he noted.

...critics were quick to ask questions about the inspection and healthcare accrediting process. Both JCAHO and CAP were publicly identified and castigated.

At this point, all inspecting agencies are sensitive to these types of criticism. State inspectors had been in the MGH laboratory in November 2003 and did not identify problems during that visit.

Yet, the inspection report made public by the Maryland Department of Health on April 2 contains 60 pages of both serious failures and minor operational deficiencies in the operation of the MGH laboratory. The state has ordered the hospital to take immediate corrective actions or face civil penalties of $10,000 per instance or per day.

On March 19, 2004, Maryland General Hospital retained consulting firm **Park City Solutions** to become interim manager of the laboratory and implement corrective actions. In early April, Laboratory Director James Stewart was put on a two-week administrative leave and then resigned, according to a hospital spokesperson.

Philip Whalen, M.D. has also resigned as the Medical Director of the MGH laboratory. In the state inspection report, it was noted that "based on a review of records, review of procedures and interview, the laboratory director did not provide overall management of the laboratory." Whalen will be replaced by pathologist John Braun, M.D.

Less Public Tolerance

This hospital laboratory's problems trigger three important observations. First, public tolerance for errors and system failures which put patients at risk is disappearing. The level of public debate and comment about the administrative failings within Maryland General Hospital over this matter is substantial—and unusual.

Second, critics were quick to ask questions about the inspection and healthcare accrediting process. Both JCAHO and CAP were publicly identified and castigated by both the local press and state health officials. That is also unusual. It may be a sign of changing public expectations about healthcare quality.

Third, problems within the laboratory itself are a major concern. These circumstances are extraordinary within the laboratory profession. Yet it is important for a detailed evaluation to be done about this situation. Understanding how this lab failed may provide priceless information that other laboratories can use to improve their quality and reliability. TDR

FL Medicaid Lab Bid Gets Slammed By Foes

Opposition builds to the planned award of a three-year, $100 million lab test contract

CEO SUMMARY: Florida laboratories were caught by surprise last month when state Medicaid officials announced a 28-day process to award one lab with the state's non-hospital Medicaid testing. To fight this RFP, a growing coalition of laboratories, lab industry trade groups, and the Florida Healthcare Coalition has taken swift steps to hire a lobbyist, gain press coverage on the issue, and meet with state policy-makers.

THINGS ARE HEATING UP in Florida. The state's proposal to place all Medicaid laboratory testing into a single contract with a single laboratory is generating growing opposition.

The laboratory industry was startled to learn last month that Florida's **Agency for Health Care Administration** (AHCA), which administers the Medicaid program in Florida, wanted to award a single laboratory the sole right to do all non-hospital Medicaid testing in the state. The contract would be for three years and is worth an estimated $100 million. *(See TDR, April 5, 2004.)*

"Each week brings new developments in this story," stated Philip Chen, M.D., Ph.D., CEO of **Cognoscenti Health Institute**, a laboratory based in Orlando, Florida. "At this moment, the process of accepting bids and selecting a winning laboratory is still officially under way. But protests and other efforts to stop this RFP are causing delays in the original timetable. AHCA will not meet an April 28 deadline for submissions, and that deadline was extended from March 28."

At least 160 laboratories currently provide testing for Florida's Medicaid beneficiaries. Many of these labs state publicly that losing access to Medicaid patients will cause them to close their doors.

Only Three Lab Bidders?

On the other hand, Florida lab executives believe only three laboratory companies are in a position to bid for the contract and have a reasonable chance of developing the statewide network required to service Medicaid patients. They are **ESRD Laboratory** in Fort Lauderdale, a lab which does testing for its parent company's dialysis patients, **Laboratory Corporation of America**, and **Quest Diagnostics Incorporated**.

"In Florida, a coalition of interested parties is working to oppose this RFP process," said Chen. "Included in the coalition are at least 30 Florida laboratory companies, with more expected. The **Florida Coalition on Healthcare**, representing employers with over two million employees in Florida, is involved. We've also gotten support from the

American Clinical Laboratory Association (ACLA) in Washington, DC.

"We've engaged John Thrasher, former Speaker of the Florida House of Representatives, to be our lobbyist," continued Chen. "Meetings have also taken place with Alan Levin, Deputy Chief of Staff to Florida Governor Jeb Bush. With such short deadlines before ACHA's scheduled award of the RFP, we've had to scramble to get our message out."

Interest in Joint Ventures

Opponents to the proposed Medicaid lab testing RFP are united around key concerns. "For example, there are no requirements in the RFP that adequately address quality in all dimensions: integrity of lab test results, patient access to collection centers, stat lab testing capabilities, turnaround time requirements, IT reporting functions, and the like," explained Chen.

"There are also concerns that the entire RFP process is a consequence of well-intended, but misguided beliefs about how a sole-source lab contract might lower lab testing costs—but without giving equal consideration to other costs related in shifting this testing away from existing labs that may add cost to the Medicaid program," Chen said.

Short Fuse Before Award

As of press time for this issue of THE DARK REPORT, the deadline for submitting RFPs was April 28 and the scheduled date for announcing the contract award is May 27, 2004. Opponents of this proposal recognize there is not much time to argue their position and stop or alter the RFP in beneficial ways.

"In Florida, laboratories are learning a painful lesson," observed Chen. "There has never been a statewide laboratory association comparable to the **New York State Clinical Laboratory Association** (NYSCLA) or the **California Clinical Laboratory Association** (CCLA). At a minimum, the need to have such a trade group to communicate with our elected officials has become obvious."

Florida Medicaid's attempt to implement a sole-source, statewide laboratory services contract should be a warning flag to laboratories in other states. So long as the quality of laboratory testing is considered "equal" from any accredited laboratory, healthcare bureaucrats can conclude that only price differentiates one lab from another. That gives them the incentive to direct their state's Medicaid lab tests to labs offering the lowest price. TDR

Contact Philip Chen, M.D., Ph.D. at 407-882-0212.

FL Medicaid Officials Explain the Lab RFP

FLORIDA'S MEDICAID BUREAUCRATS ARE beginning to explain the reasons why they favor awarding a single laboratory the exclusive right to do all Medicaid testing in the state of Florida for three years.

Cutting costs is the primary driver. In an interview in the *Miami Herald*, Florida Medicaid Director Robert Sharpe stated that budget projections indicate that Florida's Medicaid program will spend $108 million in laboratory tests during the next three years. His department, the Agency for Health Care Administration (AHCA), estimates that the statewide lab testing RFP will come in at about $100 million. That would be savings of $8 million, or about 7.2%, over the life of the contract.

Sharpe declared that another reason for selecting a single laboratory is to gain "real-time reports on lab tests to Medicaid [beneficiaries], so that information can be compared to a patient's use of prescription drugs, to see what's working and what isn't." That data is essential if we are going to cut down our drug spending," declared Sharpe.

Lab Contracting Fracas In British Columbia

Spectre of province-wide competitive bidding looms following attempted lab fee cuts of 20%

CEO SUMMARY: Government healthcare officials in British Columbia are taking definitive steps to recast the existing status quo between private commercial laboratory companies and public (government) hospital laboratories in the province. Although the stated goals are to reduce the cost of laboratory testing, the proposed means to realize these savings may prove disruptive and counter-productive.

By June Smart

WHEN IT COMES TO SQUEEZING money from the laboratory industry, Florida's Medicaid bureaucrats have nothing on healthcare officials in the western Canadian province of British Columbia.

Battle lines were first drawn on September 1, 2003, when, by bureaucratic fiat, a fee cut of 8% on laboratory tests became effective. This was to be followed by a further 12% fee cut for implementation on April 1, 2004. For now, these cuts have been reversed by British Columbia's highest court as inconsistent with the Canadian Medicare system. But the attempt to cut lab test reimbursement by 20% represents just the opening skirmish in a battle with major implications for laboratories in both Canada and the United States.

Competitive Bidding

British Columbia's (BC's) **Ministry of Health** has proposed a competitive bidding plan for laboratory testing services in the province. In August 2003, it organized an agency called the **Provincial Laboratory Coordinating Office** (PLCO). It was given the mandate to identify and recommend reforms which would improve the organization and delivery of laboratory testing services in British Columbia.

"If this competitive bidding plan is followed, radical changes will take place to laboratory services in the province," declared Douglas Buchanan, Managing Director and CEO of **BC Biomedical Laboratories**, Surrey, British Columbia. "What is unsettling is that these proposals have the potential to disrupt testing activities while reducing both patient access and the level of patient care we can offer in lab testing services. Moreover, what the government is actually achieving is a one-time beauty contest leading to a long-term monopoly situation, marked by even less competition.

"Existing funding for lab testing will now go through the six regional health authorities," he continued. "Each health authority is to have a contract tender [RFP] process in place for outpatient laboratory services by October 2005. Inpatient laboratory

services are another area under consideration for the competitive process, including surgical pathology, cytogenetics, and transfusion medicine."

Opponents Organize

Opposition to these plans is substantial. "Laboratories and other interested parties came together under the aegis of the **British Columbia Medical Association** (BCMA)," noted Buchanan. "BCMA supports the government's need to reduce healthcare costs. To achieve the province's desired cost reductions in lab testing services, BCMA submitted a proposal to aid in achieving those goals without compromising patient care or services.

Some individuals within the province believe one motive behind the government's fee reduction and tender plans is to squeeze out the private, for-profit labs in favor of publicly-owned laboratories.

"The proposal was developed with input from pathologists and lab service providers across the province. It was also supported by the **BC Association of Laboratory Physicians**. Their proposal was designed to realize the government's stated goal of $180 million in savings over the next three years—without compromising quality, access to services, and without dismantling the highly effective lab system currently in place," stated Buchanan.

To date, BCMA's proposal has gone nowhere. On March 5, 2004, the provincial government rejected the proposal and continued its plans to have each of the six health authorities issue a lab services tender by year end.

British Columbia has a dynamic private laboratory sector. The two largest labs in the province are **MDS Metro Laboratories** and **BC Biomedical Laboratories**. Both are private and have central laboratories in the Vancouver metropolitan area. Some individuals within the province believe one motive behind the government's fee reduction and tender plans is to squeeze out the private, for-profit labs in favor of publicly-owned laboratories.

"Government policy toward laboratory services has changed in fundamental ways," explained Buchanan. "In the past year, it conducted a superficial study and, among other things, concluded it was paying too much for health services. That's why laboratory services were separated from physician payments and will be competitively bid this fall.

"Along with the private laboratories, major competitors in this process are the health authorities themselves and the hospital-based laboratories under their jurisdiction," he continued. "But commercial laboratories from the United States may also join in the bidding process. That opens the possibility that lab specimens from British Columbia could cross the border to be tested within U.S. laboratories.

Details Not Yet Public

"Another troubling aspect is that details about the bidding process have not yet been made public," added Buchanan. "We are not sure how comparisons will be done; that has not been explained. However, we do know it is difficult to determine the true cost of performing tests in a hospital setting. One reason is that their capital funding comes from a separate health service budget. So how private laboratories will be compared against the health authority labs is a mystery at this time."

Laboratories in British Columbia have alerted the public to the potential

consequences of a poorly-implemented lab services tender program. "More than 200,000 British Columbia residents signed petitions of support for the present system, a system which has worked well for over 40 years," observed Buchanan. "To date, the government has failed to respond to the expressed wishes of the community, physicians, and laboratories. Because laboratory services are a critical component of the BC healthcare system which is not broken, many ask 'why disrupt a system that functions well?'"

THE DARK REPORT observes that the British Columbia situation mirrors a parallel trend in the United States. Laboratory testing is increasingly considered to be a commodity by private health insurers, government healthcare programs, and policymakers, both elected and appointed. When all lab testing is considered "equal", competitive bidding, generally a tool used to achieve lowest price, becomes the desired approach.

Lowest Price As A Goal

This is certainly the motive in efforts by Medicare and the Florida Medicaid program to implement competitive bidding for laboratory testing services within the United States. In that regard, these agencies are following the same path already trod by HMOs and managed care companies during the past 15 years.

Buchanan and his colleagues are closely watching what happens in the US with competitive bidding and how it affects the winners and losers in this war on cost. Will a "one-laboratory system" trigger "price creep?" Or will selection of a single laboratory lead to real cost savings, improved service and better patient care? Alternatively, if that doesn't happen, will the draconian restructuring of laboratory services around a lowest bidder actually cause the quality of lab testing services to deteriorate? Stay tuned, because answers may be forthcoming if BC implements its announced intentions.

The interesting twist to competitive bidding in British Columbia, compared to the Florida Medicaid situation, is that government laboratories (within government-owned hospitals) will be included in the bidding. Because a government agency is setting terms and making awards, conflict of interest claims may be inevitable. TDR

Contact Douglas Buchanan at 604-507-5120.

PLCO's Goals Include Lower Costs, Integration

PLCO IS THE GOVERNMENT AGENCY behind the British Columbia laboratory brouhaha. PLCO stands for Provincial Laboratory Coordinating Office. It was created last year.

It has broad objectives. PLCO is chartered "to develop a common foundation and framework for the delivery of high quality, accountable, sustainable, and affordable services." These are to include "availability/proximity of lab services to other patient services; availability of technical expertise; quality and sophistication of testing methodology; medical supervision and consultation; and the need for an efficient information interface with the ordering physician."

PLCO has obtained five years worth of outpatient laboratory data from public and private laboratories, which includes testing from physician offices and hospital outpatients. Test classification systems are being developed. To date, three are completed; chemistry, hematology and microbiology. Work is ongoing to finish the remaining test classifications. Test categorization is to be linked to the test volume database as a way to help in costing analysis and overall planning.

Informatics Update

Dept. of Defense and VA Prepare to Pool Health Data

Laboratory test results comprise a major portion of the electronic patient record

IT'S ANOTHER IMPORTANT STEP on the road to a true "universal patient medical record." Two government agencies are preparing to consolidate access to separate pools of healthcare data.

Earlier this week, the **Department of Defense** (DoD) and the **Department of Veterans Affairs** (VA) announced two pilot projects that, for the first time, will allow physicians working in the health system of each agency to use a single portal to electronically access their patients' medical records in either agencies' data base.

"One pilot project involves the **North Chicago Hospital** of VISN 12 in the VA and the **Great Lakes Naval Station**, also located in North Chicago," stated Bruce Dunn, M.D., Director of Pathology and Clinical Laboratories for VISN 12. "A second pilot project will take place on the west coast. It involves the **San Diego Naval Station** and the San Diego VA Medical Center."

"The information exchange between these two departments is part of an initiative which started in 2000," explained Dunn. This program has several objectives. First, the DoD wants the capability to provide a continuous medical record for service personnel and their families, regardless of where they are stationed in the world. Second, the electronic medical records of service personnel should be accessible by the VA, whenever it provides continuing healthcare.

"This is a significant undertaking," noted Dunn. "Projections are that the DoD's data base system will hold information on up to 9 million military personnel and dependents. Storage needs are estimated to be as much as 50 petabytes of data. Experts involved in this project say that, if this data were printed as text on both sides of a piece of paper, there would be enough paper to reach the Moon and back to Earth twice!"

DoD's Healthcare Initiatives

This initiative once again places the DoD and the VA in the forefront of advancing healthcare's evolution toward an all-electronic system of information management. Unlike most hospitals in the private sector, which still have paper medical records, the DoD has used electronic medical records for 10 years. However, data is currently stored at each individual facility. Pilot projects like the ones mentioned here are steps to achieve better integration and access to clinical data.

THE DARK REPORT observes that the two pilot projects represent another stage in the military's initiative to use LOINC (Logical Observation Identifier Names and Codes) to link laboratory test results across all military hospital laboratories across the world. *(See TDR, June 24, 2002.)* This important story will be updated as appropriate. TDR

Competitive Bidding: A Growing Threat to Labs

It's popping up in more regions as government health programs look for ways to save money

CEO SUMMARY: When it comes to competitive bidding for laboratory testing services, Medicare is no longer the only government health program looking to save money through this method. Florida's Medicaid program and the British Columbia health system are both moving forward with plans to implement competitive bidding. Skyrocketing healthcare costs may make this an unstoppable trend.

HAS COMPETITIVE BIDDING'S TIME finally come? Is this an idea which can no longer be stopped?

For years, the laboratory industry has opposed Medicare's plans to implement a demonstration project to competitively bid laboratory testing services. To date, lobbying efforts have kept such a demonstration project on the back burner.

But now, within a few months of each other, there are two additional examples of government health programs moving determinedly to a large-scale competitive bidding process. In March, Florida's **Agency for Health Care Administration** (AHCA) announced an RFP for all that the state's non-hospital laboratory testing. The contract, estimated to be around $100 million, will award a single laboratory with all Medicaid lab testing business for three years. *(See pages 8-9.)*

It's a similar story in British Columbia. Last year provincial health officials announced two lab test fee reductions totaling 20%. They also declared that testing for non-inpatients would be put out to bid. Private laboratory companies in the province will be competing against labs operated within government-owned hospitals. *(See pages 12-12.)*

California can be added to this list, but with a slightly different twist. Its Medicaid program wants to attack fraudulent claims from tiny labs which pop up and disappear with regularity. To improve its control over laboratory providers which submit claims, it is revamping its contractual relationship with laboratories.

Increased Demand & Costs

Collectively, these examples show that contract bidding for lab services provided to government health programs may be an inevitable consequence of two trends. Healthcare costs are rising and demand for healthcare services in government health programs like Medicare and Medicaid is outstripping existing funding capabilities. The incentive to cut costs is obvious.

Florida's Medicaid program faces a severe budget constraint. Last year it

spent more than $14 billion. It expects to pay an additional $1.4 billion this year. The budget crunch in British Columbia is equally severe. In recent years, Canada's federal government has significantly reduced the funding it sends to the provinces to fund healthcare services. This has left provinces like British Columbia with an unanticipated shortfall in available funds for covering the cost of healthcare.

Justifiable Concerns

The laboratory industry is rightfully concerned about a government-designed, government-managed competitive bidding program. The contract awards process can be biased. One source of bias is the lack of expertise to design an effective, fair RFP. Another source of bias can be found in the design an RFP, which can be structured to favor one class of laboratories over another.

Of course, there is another aspect of competitive bidding that strikes laboratories in the United States as "unfair." That is the fact that such bidding programs limit choice by physicians and patients. By nature, Americans are a people who like choice. They also do not like to be told that they must accept a single option. Because a government-run competitive bidding program, by definition, restricts or even eliminates choice, it is easily criticized by private enterprises.

Incentives To Continue

Despite the laboratory industry's dislike of competitive bidding, a number of market signs indicate that this concept is not likely to disappear. As noted in the examples above, government healthcare programs are caught in the double squeeze of growing expenses (from higher utilization and increased costs) and constrained revenues (because of the inability to raise tax rates). Competitive bidding is a logical device for government health program administrators to use to constrain price pressures.

As the Florida Medicaid example shows, the laboratory industry in the United States is unprepared to deal with the emergence of competitive bidding programs in state Medicaid programs. It has neither the experience in opposing these initiatives nor the collaborative lobbying resources to rapidly bring effective opposition to bear.

Of equal importance, the laboratory profession does not have close links to those establishing policy within the Medicaid programs of most states. Thus, a proactive capability to blunt competitive bidding programs before they are announced is lacking.

Despite the laboratory industry's dislike of competitive bidding, a number of market signs indicate that this is one concept which will not disappear.

For these reasons, the lab industry seems about to enter a "trial and error" phase in regards to competitive bidding. What will make this process particularly trying is the difference between Medicare and Medicaid.

Every state's Medicaid program will reflect local circumstances, needs, and healthcare practices. In contrast, the existing laboratory industry lobbying coalition has a fair idea of how the decision-making process happens within the Medicare program. It cannot be assumed that lobbying strategies that get the attention of Medicare officials will work equally well with state Medicaid administrators. That will make it more challenging for laboratories in different states to have their voices heard on this important issue. TDR

Lab Industry Briefs

SPECIALTY LABORATORIES SHOWS VOLUME GROWTH DURING CALENDAR 2003

If the financial performance of **Specialty Laboratories, Inc.** in fourth quarter 2003 is an accurate measure, it appears the company has moved past its troubling problems of 2002.

For fourth quarter 2003, Specialty Labs reported modest growth in both net revenue and specimen volume. This indicates that the company is generating additional test referrals from existing and new reference testing clients.

Fourth quarter 2003 revenues were $30.5 million, compared to $29.9 million in Q4-2002. This was an increase of 2%. Accessions for fourth quarter 2003 were 628,000 versus 614,000 accession in Q4-2003. This also represented an increase of 2%.

For the full year 2003, net revenue at Specialty Labs totaled $119.6 million, a decline of 14.7% from 2002's $140.2 million. The company showed an operating loss in 2003 of $10 million, compared to a loss of $22.8 million in 2002.

What these numbers mask is another significant accomplishment by Specialty Labs during 2003. **Unilab Corporation** was Specialty Lab's single largest client, representing as much as $17 million in annual revenues. In February 2003, **Quest Diagnostics Incorporated** became the owner of Unilab. It began redirecting Unilab's send-out testing to other laboratories within Quest Diagnostics.

Thus, Specialty's 2% increase in specimen volume between fourth quarter 2002 and 2003 represents a substantial increase in specimens referred by existing and new clients. That additional increase was enough to offset the ongoing reduction of send-out volume coming from Unilab.

Specialty Laboratories also has a new Chief Financial Officer. Last month it announced that Kevin R. Sayer had joined the company. Sayer was at **MiniMed, Inc.**, a company with services in diabetes management.

MAJOR LEAGUE BASEBALL, BARRY BONDS, AND QUEST DIAGNOSTICS

MAJOR LEAGUE BASEBALL'S PROBLEMS with steroid use has generated big headlines. In San Francisco, a federal grand jury probe of steriod use in baseball and the **Bay Area Laboratory Co-Operative** (BALCO) triggered a federal raid at the **Quest Diagnostics Incorporated** laboratory in Las Vegas.

On Thursday, April 10, IRS agents entered the Quest Diagnostics laboratory and seized specimens and drug test results on specific major league baseball players. Federal agents were acting on a subpoena issued as part of the grand jury probe in San Francisco.

Informed sources told the press that IRS agents sought the specimens and test results of not more than 12 players. Among the names mentioned were San Francisco Giants' home run slugger Barry Bonds and New York Yankees players Gary Sheffield and Jason Giambi.

Quest Diagnostics' link to the major league baseball and its steriod use scandal is innocent. During 2003, Major League Baseball wanted to evaluate the extent of steriod use within the American and National Leagues. It conducted a drug testing program

that randomly selected some players for evaluation. **Comprehensive Drug Testing** of Long Beach, California handled certain aspects of this program and actual testing for drugs was done at the Las Vegas laboratory of Quest Diagnostics.

Major League Baseball determined that, of the players tested, more than 5% tested positive for steriod use. It then implemented new prohibitions on steriod use, along with a testing program and penalties for players who test positive.

Because the testing done in 2003 was part of an evaluation program, the test results were to be anonymous. That's where the federal grand jury in San Francisco comes in. As part of its probe of steriod use in baseball, the grand jury issued indictments against four individuals who allegedly distributed steroids to professional athletes. One of these indictments was against Greg Anderson, who was a personal trainer for Bonds.

The IRS raid on a commercial laboratory is an example of how law enforcement interests can create management challenges for laboratories. In emergency rooms, there are instances of law officers requesting phlebotomists to draw blood from alleged drunk drivers, even though the subject opposes the specimen collection.

CYTYC CORPORATION DOES SEVERAL DEALS TO HELP IT DIVERSIFY

WITH AN EMPHASIS ON WOMEN'S HEALTH, **Cytyc Corporation** has done three deals since the beginning of 2004.

On March 30, Cytyc and **DakoCytomation Denmark A/S** announced a collaboration to investigate a biomarker associated with cervical cancer. The p16INK4a protein "is expressed as a consequence of abnormal E7 gene activity following human papillomavirus (HPV) infection. As such, it may serve as a marker of high-risk HPV effects on the cervical epithelium." The joint agreement calls for the two companies to study the effectiveness of DakoCytomation's CINtec™ p16INK4a Cytology Kit on Cytyc's testing instruments.

Just six days earlier, on March 24, Cytyc closed its acquisition of **Novacept**, paying a net price of $311 million to purchase the California-based manufacturer of the NovaSure® System. NovaSure is an "endometrial ablation device to treat menorrhagia, or excessive menstrual bleeding."

In a third deal, Cytyc and **Abbott Laboratories** signed an agreement last January to collaborate and co-promote a combination product. Called the ThinPrep® UroCyte™ Slide Preparation System, it modifies Cytyc's thin layer sample preparation technology with Abbott's UroVision™ test, the DNA-based test for detecting recurring bladder cancer.

MOVE OVER ASCP! CONCIERGE PHYSICIANS FORM THEIR OWN ASCP

"CONCIERGE MEDICINE" IS COMING into its own. The newly-formed **American Society of Concierge Physicians** (ASCP) announced its first national conference, scheduled for May 27-28, 2004 in Denver, Colorado.

Concierge medicine refers to an evolving medical business model where patients pay a flat fee, either monthly or annually. In return, the concierge physician will see the patient whenever requested and will allow office visits to last as long as the patient wants. In most concierge medicine arrangements, insurance will not be billed by the concierge physician. Because it is a cash-and-carry business, concierge physicians make good client accounts for labs. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Pathology gets another plug! CBS television recognized National Medical Laboratory Week with public service announcements (PSAs) featuring *CSI: Crime Scene Investigation* star William Peterson. The story behind the story is that Peterson asked CBS to cover production costs and broadcast time to allow him to say something about the laboratory staffing shortage and to salute pathologists and laboratory professionals across the country. Peterson's interest was spurred by his interaction at last September's annual meeting of the **American Society of Clinical Pathologists** (ASCP) in New Orleans.

MORE ON: Peterson

During the ASCP meeting, Peterson received the ASCP Special Recognition Award. In a recent interview in *Playboy Magazine*, Peterson made a surprising revelation. "I was invited to receive an award at the American Society for Clinical Pathology in New Orleans. It's the best award I've ever gotten—way better than an Emmy!"

BIG SPENDING "ZOOMERS" EMERGE FROM BABY BOOMERS

Last month, TDR introduced you to "Zippies." This term describes the upwardly-mobile, highly educated young people manning telephone calling centers in India. Now it's time for you to meet "Zoomers!" This term is used by some corporate marketing departments to describe baby boomers with money to spend. What makes zoomers important to laboratories is that they have adequate income and consider healthcare to be a luxury good that enhances their quality of life. Among other things, zoomer spending is fueling the growth of health-related procedures such as botox injections and plastic surgery.

ADD TO: Zoomers

Zoomers represent the economic spearpoint of aging baby boomers. Statistics tell the story. In 2001, 78 million Americans were aged 50 or older. According to data from the Federal Reserve and the U.S. Census, this group controlled 67% of the nation's wealth, or about $28 trillion! What's particularly interesting is that, in households headed by a member of the 55-to-64 age group in the year 2000, median net worth was $112,048. That's 15 times the median net worth of $7,240 reported for households headed by someone in the under-35 age group. Demographic trends project that, in just five years, one-third of the U.S. population will be at least 50 years old. Two predictions: consumer mass marketing will increasingly target seniors and ads for prescription drugs and healthcare services directed at seniors will increase exponentially in coming years.

• Over in Springfield, Massachusetts, **Baystate Health System** is looking for a new laboratory administrator. Long-time laboratory director Douglas Jaciow resigned from his position at Baystate earlier this month.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 17, 2004.

THE DARK REPORT

UPCOMING...

- *THE DARK REPORT'S Annual Ranking of Public Lab Companies: a Short List.*
- *Competing Labs in British Columbia Use LOINC to Collaborate for Physicians' Benefit.*
- *How Molecular Diagnostics Is Finding Clinical Acceptance: First Insights from the* **Executive War College.**

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