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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Warning Ahead: Investigation And Litigation

NEWS THAT PRIVATE INSURERS FILED A MAJOR LAWSUIT against SmithKline Beecham last Thursday confirms something I've wondered about for several years. What would be the private insurer's perspective on the same laboratory billing and reimbursement practices which triggered federal settlements with major laboratories?

Now we know. The opinion of private insurance companies is that they were ripped off, just like the Medicare program. It is highly significant that huge insurance companies such as **Aetna**, **Prudential**, **New York Life Insurance**, **Blue Cross of California** and **Humana** joined together to sue SmithKline. They must believe they have a strong legal case.

This lawsuit marks the start of another phase of laboratory industry compliance. Federal prosecutors are applying the lessons learned from the Ohio hospital laboratory billing probe by launching similar probes in Georgia, Maine, Mississippi, Rhode Island, Vermont, Virginia and the District of Columbia. Private insurance companies have targeted one national laboratory for their first case. Taken together, these events mean that ever-smaller laboratories should not be surprised to find themselves involved in some type of settlement discussions in coming years.

THE DARK REPORT covers these these events because it is important for laboratory executives to understand what is really taking place behind the headlines. Compliance is now a major element of clinical laboratory management. Failure to properly comply with the law may now mean more than just paying money back to Medicare for alleged over-reimbursement. It may mean criminal charges against individual executives.

That is one reason the **Columbia/HCA** case bears close scrutiny. Even as federal prosecutors become wiser about how the healthcare reimbursement system traditionally operated, they are becoming emotionally involved. Prosecutors are increasingly angry about healthcare executives they believe consciously "gamed" the reimbursement system to "steal" millions from government health programs. Such anger motivates prosecutors to bring criminal charges against alleged violators.

Thus, the news that government prosecutors widened the hospital laboratory billing probe to six more states, combined with the announcement of the large insurance companies' lawsuit against SmithKline means at least one thing: laboratories will be dealing with the alleged reimbursement sins of 1989-1995 for several more year. TDR

Issues At Columbia/HCA Exist At Other Hospitals

Prediction that whistleblower lawsuits already play a major role in federal investigation

CEO SUMMARY: Even as federal regulators attract big headlines in their investigation of Columbia/HCA, laboratory administrators in a variety of hospital setttings may be surprised in the future to find federal investigators scrutinizing the billing practices at their institution. Columbia's investigation reveals that federal prosecutors will use precedents in earlier laboratory billing cases as a key part of future cases.

NASHVILLE'S **Columbia/HCA Healthcare** continues to dominate national news reports of healthcare fraud and abuse.

Although laboratory billing practices will continue to play an important role in this case, several other reimbursement practices are getting attention from federal investigators. The untold part of this story is the role whistleblowers now play in tipping federal investigators where to look and how to proceed.

THE DARK REPORT has predicted the increase of whistleblower lawsuits involving laboratory practices. When **SmithKline Beecham** agreed to pay $325 million to the federal government in February of this year to settle claims of Medicare fraud and abuse, at least four separate whistleblower lawsuits were involved.

It is difficult to know how many whistleblower lawsuits have been filed that identify laboratories or hospitals as violators of Medicare/Medicaid fraud and abuse statutes. Whenever a *qui tam* lawsuit is filed by a whistleblower, it becomes sealed until the **Department of Justice,** after its own investigation, decides not to join the case.

Notwithstanding that fact, THE DARK REPORT believes there is an ever-growing number of whistleblower lawsuits. Press reports reference how insiders helped government investigators prepare for raids on Columbia's facilities and offices. It is a safe assumption that at least a few of these individuals now helping the government had earlier filed a *qui tam* lawsuit, thus informing the government about what they know as well as where to gather evidence necessary to prosecute the case.

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Probably the leading attorney on the subject of whistleblower lawsuits is John Phillips of **Phillips & Cohen** in Washington D.C. "I cannot comment about any specific whistleblower lawsuits that I may be involved in," stated Phillips, "but it can be said that increased attention and focus on certain billing practices of hospitals, combined with publicity about successful whistleblower lawsuits, is causing more such lawsuits to be filed.

"In our experience, as the public becomes more informed about whistleblower lawsuits, the number of those suits increases," he added. "This is precisely what Congress intended when it passed legislation in 1986 strengthening the whistleblower procedure."

According to Phillips, the Columbia case illustrates two basic types of healthcare fraud which will attract the most attention by investigators and prosecutors. "I believe you are going to see the whole area of cost-reporting undergo extensive investigation. The practice of illegally inflating cost reports is widespread among hospitals throughout the country and for years was virtually unaudited by HCFA."

"In our experience, as the public becomes more informed about whistleblower lawsuits, the number of those suits increases."

-John Phillips

In fact, the first indictments in the Columbia case involved allegations of fraud in cost-accounting for a Florida hospital owned by the company.

"Because many hospitals kept an additional set of 'confidential' cost reports to reserve for potential adjustments in what they claimed in their 'as submitted reports,' federal investigators will have a paper trail to seek and examine each facility's handling of cost accounting claims year-by-year. This makes it easier to build a successful case against the hospital.

"Although it is a complex process to apply for reimbursement under Medicare's Part A cost accounting guidelines, I believe that a significant number of items submitted will be found to be clearly improper. Per the news reports on the Florida case, the charge is that the executives 'knowingly' sought reimbursement for claims to which they knew, under law, they were not entitled. 'Knowingly' is the key. If the government can make that case, then those actions will be judged as fraud."

Widespread Practice

"I suspect that, in the area of cost accounting, the government will find this practice to be widespread. Dollars paid to hospitals under cost accounting reimbursement guidelines were immense," explained Phillips. "Thus the government's potential recovery could be significant, particularly as these fraud investigations will go back ten years. A typical hospital's cost-accounting involves about $2 million per year in reimbursement. If 30% to 40% is determined to have been fraudulently submitted, then the dollars add up quickly for prosecutors, particularly with treble damages."

Just as cost accounting has a clear paper trail that helps prosecutors prove their case, so also do laboratory billing practices offer a similar paper trail. Because of established precedents and the relative ease of documenting such cases, Phillips believes laboratory billing practices will play a significant role in prosecutor's cases against hospitals.

Pamela Bucy agrees with Phillips. She is a health-fraud expert on the faculty of the **University of Alabama Law School**. Bucy noted that the

Columbia investigation is becoming a multi-agency effort. Besides the **HHS Inspector General's Office**, the **U.S. Postal Service** and the **Defense Department's** criminal investigation service are also involved in the Columbia probe. Various state agencies are participating as well.

Bucy says that, should the government choose to pursue laboratory billing practices at Columbia, the multi-agency approach helps. "If all they can come up with are isolated problems, it will be hard to show fraud instead of just honest mistakes. But if they can establish a persistent pattern of problems, they will have a stronger case."

As reported in the last issue of THE DARK REPORT, prior to the July raids on Columbia hospitals, emergency room physicians employed by the company stated that they had been interviewed by FBI agents concerning CBC ordering patterns, whether more laboratory tests were performed than ordered, and whether the tests performed were medically necessary for the patients involved. *(See TDR, August 4, 1997.)*

Largest Company

As in the Labscam series of cases involving the largest commercial laboratories, government investigators have started with the largest hospital operator in the United States. Stock analysts are now beginning to publicly state that the settlement between Columbia and the government could well exceed $1 billion. There will also be a surprising number of criminal indictments filed against Columbia executives.

Once investigators complete the Columbia case, they will turn their attention to other hospital chains and smaller clinical laboratories. This process is already underway. According to the Justice Department, FBI healthcare fraud investigations climbed to 2,200 in fiscal 1996, compared to 657 in fiscal 1992. Civil investigations into healthcare fraud by the Department of Justice increased by ten-fold over the same time period, from 270 in 1992 to 2,488 in 1996.

Laboratory executives should carefully note the change in attitude by government regulators and prosecutors. The historical rules of the reimbursement game are rapidly changing. Whistleblower lawsuits add more uncertainty. Because of the increased use of criminal indictments, any laboratory, whether hospital or commercial, nailed by prosecutors for improper billing and reimbursement practices, faces possible criminal charges along with civil penalties. TDR

(For further information, contact John Phillips at 202-833-4567.)

Prosecutors Looking At Five Basic Issues

In the Columbia/HCA investigation, at least five significant areas of operation are undergoing scrutiny.

1. Cost Accounting: This involves how overhead expenses were defined to qualify for reimbursement under Medicare guidelines.
2. Laboratory Test Unbundling & 72 hour DRG Window: These allegations of laboratory fraud and abuse are based upon earlier settlements with clinical labs and hospitals.
3. Upcoding: This is a new area of investigation. Reimbursement records will help prosecutors build their case.
4. Referral Arrangements: These cases will be tough, as inducement and Stark amendment violations are difficult to prove.
5. Home Healthcare Procedures: Major new area for investigations of fraud and abuse.

Tennessee Lab Network To Become Operational

Another regional lab network model completes strategic business plan, schedules start date

CEO SUMMARY: Although news of regional laboratory networks disappeared from the pages of lab industry publications, the movement is far from dead. In Tennessee, 13 hospital laboratories are about to launch the Middle Tennessee Healthcare Network. Organizers believe they have solutions to the management problems which plagued early networks.

THREE YEARS OF EFFORT is about to bear fruit. Organizers of Nashville's **Middle Tennessee Healthcare Network** (MTHN) expect CEOs of the parent hospitals to bless the completed business plan and authorize formal launch of operations within the next 60 days.

It will be one of the larger regional laboratory networks to achieve operational status during 1997. Eleven hospital systems own equity. A total of 13 hospital laboratories will provide testing services to the Central Tennessee area.

Started in 1994

"We started on this road in June 1994," recalled Ran Whitehead, Laboratory Administrator at Baptist Hospital and a member of MTHN's executive steering committee. "At that time a number of hospitals were exploring ways to combine efforts to counter marketplace pressures of managed care and **Columbia/HCA**.

"It was JoAnne Schroeder, the laboratory administrator at **Maury Regional Hospital**, who got lab administrators at five of the original nine hospitals to meet and discuss the viability of a laboratory network," he continued. "As the group studied their business options, they quickly realized the vulnerability of their existing contracts for outreach testing.

> ***"With a professional sales and marketing program, we felt the network could double that volume of business for its members..."***

"From the start, a major goal of the Middle Tennessee Healthcare Network was to protect existing managed care contracts and pursue additional managed care work," added Whitehead. "A market feasibility study was completed by the summer of 1995. According to this study, our member hospital laboratories held 13% of the market share for outreach laboratory testing. With a professional sales and marketing program, we felt the network could double that volume of business for its members."

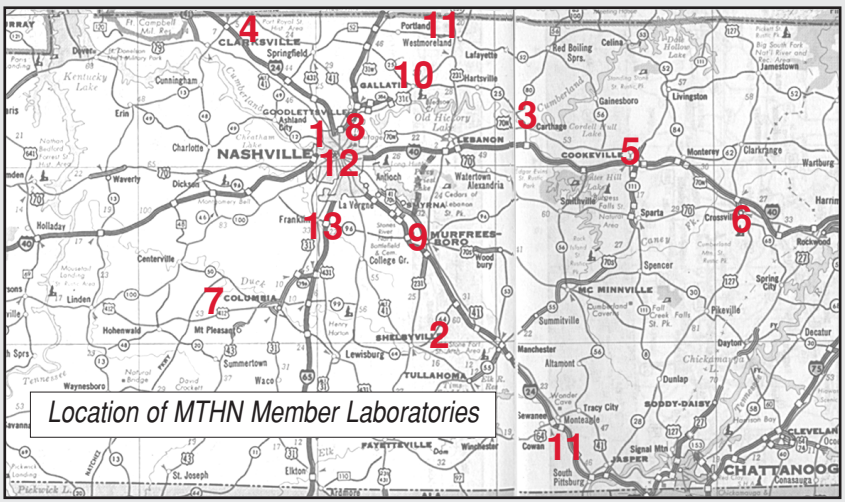
Once specific business goals were identified, the next step was to develop a business plan and determine the organizational structure for the model. "From the start, we looked at all options," declared Kim Charlton, Laboratory Administrator at **St. Thomas Hospital.** "We considered logical partners, such as

Regional Lab Network In Tennessee

Middle Tennessee Healthcare Network will provide laboratory services to central Tennessee, including Nashville. A major competitor is Columbia/HCA, which operates 6 hospitals around greater Nashville. Laboratory Corporation of America has the largest market share of outreach laboratory testing in the Nashville market.

Hospital Laboratories Participating In The Middle Tennessee Healthcare Network

1. Baptist Hospital
2. Bedford County Hospital
3. Carthage General Hospital
4. Clarksville Memorial Hospital
5. Cookeville General Hospital
6. Cumberland Medical Center
7. Maury Regional Hospital
8. Middle Tennessee Healthcare Network
9. Middle Tennessee Medical Center
10. Summer Regional Hospital
11. Tennessee Christian Medical Center
12. Vanderbilt University Medical Center
13. WIlliamson Medical Center



Location of MTHN Member Laboratories

reference laboratories. We also began to focus on strategic business models which would best fit our needs.

"For example, should the network operate a shared esoteric laboratory," she asked, "or should there be centers of excellence, with testing shared across a number of laboratory sites? These were difficult questions because political as well as operational consequences surrounded every option.

"It was about this time that the hospital network hired an executive to support the various business initiatives under discussion at the network," said Whitehead. "Roy Wright became the executive director in December 1995. Because the laboratory network concept was recognized to be a feasible project, Roy made it his priority."

The first business plan was developed during the summer of 1996. Experts assisting to develop the business plan recommended a common laboratory information system, accompanied by a $6 million price tag. "That caused some of the participating hospitals to become resistant to spending such large sums of

money relative to the expected return," noted Whitehead. "It made us rethink how we wanted to use the capital which the hospitals were willing to provide."

Challenge Assumptions

The solution was to assign one laboratory manager with the task of challenging the assumptions in the business plan, developing vendor contracts and commitments, then proposing a capital budget and spending plan. "One laboratory administrator was delegated by the board to tackle this project. Her hospital released her from regular duties for 90 days so she could devote full time to study the business plan and implement the necessary action items."

Kim Charlton, assisted by Whitehead, Schroeder and Wright, assumed responsibility for this project in November 1996. By February 1, 1997, RFPs (request for proposals) were issued for several business services. These included reference laboratories, LIS options, courier arrangements, legal opinions as to organization structure, esoteric testing and marketing resources.

"A key element for the network was its choice of a reference laboratory partner," stated Charlton. "The partner had to be willing to share risk with the network and connect ten disparate LIS systems. An intense RFP process resulted in the choice of **Specialty Laboratories**. Our network will share risk with Specialty, operate a combined courier system, offer dedicated customer service support, LIS solutions and Specialty will participate on the network's operations council.

"It was a full-time effort to accomplish this in 90 days," stated Charlton. "In February, we provided the board with recommendations on three basic issues: two reference laboratory partners, specific capital needs and the organizational structure for the network. There was unanimous approval to proceed."

That was the point at which the participating hospital systems could opt in or out as an equity participant. Eleven of the thirteen chose to become equity participants.

The regional laboratory network is chartered as a limited liability company (LLC). In the six months since the February meeting, implementation milestones leading to operational status became priority.

"A significant amount of legal work and review for our chosen business organization has taken place," noted Whitehead. "We are carefully developing a pricing plan for esoteric and reference testing to meet anti-trust and other regulatory guidelines. Our network does not use the messenger model for this function."

"Details for implementing the business plan were identified," added Charlton. "We also recently completed a search for the executive director of the network. JoAnne Schroeder will leave her current position at Maury Regional Hospital and become a full-time executive director for MTHN. Recruiting for our needs in sales and marketing was launched and we intend to maintain a constant presence in our market area."

Operational Launch

With the operational launch of Middle Tennessee Healthcare Network just around the corner, another model of regional laboratory services enters the marketplace. Given the politics of bringing 13 hospital laboratories into a single service organization, the three-year gestation period was not unusual.

MTHN has three traits common to successful regional laboratory networks. First is the recognition of the need for a full-time executive director, during both the development and implementation phases. Second is the emphasis on professional sales and marketing. Third is an economic structure which makes the network operationally self-sustaining. TDR

(For further information, contact JoAnne Schroeder at 615-380-4024, Ran Whitehead at 615-329-7043, Kim Charlton at 615-222-6542.)

Late-Breaking News

Private Insurers Sue SmithKline, Feds Pursue Labs In Six States

FRAUD AND ABUSE for laboratory billing is an issue which refuses to disappear. Private insurers filed a lawsuit against **SmithKline Beecham** last Thursday, seeking unspecified damages related to overcharging for laboratory testing during the years 1989-1995.

At the same time, news emerged last week that government prosecutors recently sent letters to hospitals in six states requesting a self-audit of reimbursement claims relating to Medicare/Medicaid laboratory tests.

Both developments confirm predictions of THE DARK REPORT that virtually every laboratory, whether commercial or hospital-based, will be affected by the federal government's efforts to dun the laboratory industry for past billing sins.

The surprise in the SmithKline case is that private insurers are pursuing recovery of reimbursements paid for laboratory testing during the period of 1989-1995. A consortium of large insurers claims that SmithKline overcharged them for laboratory tests. They also allege that SmithKline violated federal racketeering statues in a conscious plan to defraud private payers.

By filing charges under the RICO act (Racketeer Influenced and Corrupt Organizations act), the insurers could collect treble damages if they prevail. The potential recovery is immense. Analysts estimate insurers are seeking more than $1.5 billion in potential claims under the RICO act.

Should private insurers prevail against SmithKline, expect to see this industry consortium file similar suits against other large commercial laboratories. Once the legal precedent is established, private payers may find it worthwhile to pursue recovery from as many clinical laboratories as possible.

On the government side, dozens of hospitals in Georgia, Maine, Mississippi, Rhode Island, Vermont, Virginia and the District of Columbia were sent letters from federal prosecutors requesting a self-audit of laboratory test claims sumbited to Medicare. The process is similar to the federal investigation of hospital laboratory billing practices in Ohio reported by THE DARK REPORT during the past year.

The announcement that private insurers are willing to pursue legal claims against laboratories, combined with the federal prosecutor's expansion of the hospital laboratory billing initiative, signals that the laboratory industry will undergo more years of investigation and litigation.

What is significant about both developments is that even small laboratories may find themselves the targets of government efforts to extract a settlement involving laboratory billing issues. The additional threat is that insurers, assuming they are successful in their claims against SmithKline, could mount their own widespread campaign to collect "over reimbursement" from clinical laboratories throughout the country.

For laboratory executives, such actions by private insurers and government prosecutors should not be treated lightly. It is the belief of THE DARK REPORT that a sizeable number of laboratories will find themselves dealing with both the **Department of Justice** and private payers during the coming years. **TDR**

CEO SUMMARY: Any laboratory executive with several years in the business has confronted the limitations of laboratory information system (LIS) software. For a variety of reasons, LIS software seldom delivers the full range of benefits and cost-effectiveness sought by laboratories. But in the fee-for-service world of the past, such limitations were tolerated by the healthcare system. That is changing with managed care. As integration of clinical services evolves, it will be mandatory that both hospital laboratories and commercial laboratories become leaders in making clinical integration a reality. THE DARK REPORT predicts that any laboratory first to the marketplace with effective integrated LIS capability will achieve a dominant market position. Industry vendors with innovative integration solutions are now beginning to bring their products into the marketplace.

Innovative Approach Promises Integration of Clinical Lab Data

NO SINGLE TYPE of healthcare provider has a greater need to integrate clinical data than laboratories. In fact, the ability of a single laboratory to pass laboratory information through a variety of information systems will prove to be a significant success factor in the immediate future.

Industry vendors and laboratory executives alike consider information systems to be one of the most difficult areas to manage within the clinical laboratory.

Information systems create four problems for a typical laboratory. First, any time a laboratory wants to upgrade or change laboratory information system (LIS) software, the process is expensive, time consuming and disruptive to laboratory clients.

Second, taking orders from physician clients and reporting laboratory test results represents a major source of laboratory errors, customer satisfaction issues, compliance problems and billing/reimbursement failures. This is true whether the laboratory is hospital-based or an independent commercial laboratory.

Third, hospital laboratories want CPU-to-CPU links with their reference laboratories. When their two computers talk directly to each other, the benefits in productivity, accuracy and speed are remarkable. However, both reference laboratories and their clients find the process of creating a CPU-to-CPU link to be expensive, time consuming and difficult.

Fourth, the emergence of integrated delivery systems which seek to clinically integrate various aspects of healthcare creates a new challenge for both hospital laboratories and commercial laboratories. If laboratories cannot pass laboratory test data to all providers within the system, the laboratory becomes an impediment to clinical integration. Because more than 60% of a patient's medical record typically consists of laboratory data, it is imperative that laboratory test data flow uniformly throughout the integrated healthcare system.

Any laboratory that develops an effective solution to one of these challenges will find itself with a competitive advantage in its marketplace. A survey of existing technology and available products reveals, however, that the LIS industry has yet to develop practical, low-cost options. The next generation of LIS still must demonstrate effectiveness in actual use.

In fact, most healthcare information system vendors are racing each other to incorporate the latest computer hardware and software technology into a product which makes integration of clinical data feasible in a wide variety of organizational models.

In King of Prussia, Pennsylvania, a company called **Healthworks Alliance, Inc.** is striving to create practical software bridges between existing clinical information systems. Performance of their earliest IS networks involving hospital systems and clinical laboratories provides evidence that a cost-effective way to link clinical laboratories with other providers in an integrated healthcare system may be just around the corner.

Because clinical integration of laboratory test data is a critical success factor for laboratories, Healthworks Alliance's pioneering efforts provide evidence of the difficulties in achieving clinical integration within an integrated delivery system.

"We originally started as part of **Advacare**," stated David Tribbett, Executive Vice President of Healthworks Alliance. "This was a company which primarily offered billing and collection services to hospital-based physicians. Advacare wanted to expand that business by offering billing to physicians who were ambulatory-based as well.

"Our original business goal was to permit the hospital to leverage excess capaci-

through our software, the hospital could encourage physicians to use laboratory, radiology, cardiology and other services. We would then go to the physicians and offer to do their billing as well.

"We've been developing software to integrate clinical services since the mid-1980s," explained Tribbett. "As managed care began growing, we realized that products we developed as a way to sell billing services to physicians had greater value to hospitals and ancillary service providers in expediting clinical integration."

Separate Company

In 1992, Advacare went public. As part of that transaction, Healthworks Alliance was spun off as a separate company. "This is when our emphasis on laboratory services began," stated Tribbett. "Until then, our product was positioned as a way for the hospital to compete against commercial laboratories.

"We quickly saw the need was widespread to integrate laboratory data between the hospital and the reference laboratory. We also saw how commercial laboratories were placing computers into physician offices to create test requisitions and report results.

"We recognized that the marketplace was already linking physician to laboratory by computer," noted Tribbett. "With our experience at integrating laboratory, cardiology, radiology and other ancillary services, we believed we had an established capability to build data integration bridges between all providers in an integrated system."

Marketplace Dynamics

"We could see that marketplace dynamics would force clinical integration between two categories of providers: laboratory with its physician office client and reference laboratory with its hospital laboratory client.

For Healthworks Alliance, the first opportunity to develop workable solutions came several years ago with a contract involving **The Malden Hospital** in Boston, Massachusetts. "Malden saw its laboratory outreach business going to commercial laboratories because of managed care contracts. Our information system network has linked their ancillary services to physician offices since early 1994. Malden decided to protect their laboratory outreach business by partnering with **SmithKline Beecham Clinical Laboratories**. Both companies were to share in testing and split revenues from the contracts."

It was Healthworks Alliance's job to create an integrated data bridge between Malden and SmithKline. The goal was for physicians to order laboratory tests using one system. Specimens and data would flow to the Maulden and SmithKline laboratories from that single order system. Results from both laboratories would go back to the physician through the same system."

Partnership Dissolves

"After one year of this arrangement, for various reasons Malden and SmithKline parted ways," continued Tribbett. "But Malden still wanted to pursue outreach testing with a commercial laboratory partner.

"Malden looked at **Laboratory Corporation of America** as a potential partner. LabCorp agreed. But the challenge for Malden was how to plug LabCorp into the existing relationship with Malden's clients and not disrupt those physicians' offices.

"It was easy for us to accomplish this because our product is designed to make test directory changes invisible to the end user," noted Tribbett. "We had previously mapped Malden's test directory to SmithKline's catalog. This produced a consolidated ordering menu and a consolidated test report to the physician and ambulatory environment.

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Why LIS Is Difficult To Link With Different Info Systems

CONSIDER THE SUPPOSEDLY SIMPLE project to connect a hospital LIS with a reference laboratory LIS. Both parties eagerly want a single entry arrangement which can pass information back and forth. Yet commonly such an interface is too expensive and too time consuming to accomplish.

After all, if the reference laboratory uses **Antrim**, for example, and the hospital laboratory is on **Cerner**, **SMS**, or one of the other major systems, wouldn't prewritten interfaces already exist between these software products?

"Unfortunately, the answer is generally no," responded David Tribbett, Executive Vice President at Healthworks Alliance. "The reason is simple. Take HL-7, for example. HL-7 was designed to be a common standard for healthcare software. It is actually a well-designed code structure for laboratory data.

"But many programmers, when adapting the hospital's new information system to meet their custom needs, find it easier to write in-house interfaces using 'z segments' instead of HL-7's existing format. These are user-defined segments with user-defined fields within the segments.

"Because the hospital ends up with customized 'z segments' buried in the HL-7 code, each time an interface is needed between the reference laboratory's LIS, like Antrim, and the hospital's LIS, like **Sunquest**, the interface code literally has to be created line by line to accommodate the individualized 'z segments' found in the hospital's LIS."

As most hospital laboratory administrators know, creating such CPU-CPU interfaces with the reference laboratory often takes up to one year and $50,000. This is the key reason why relatively few CPU-CPU interfaces exist between hospital and reference laboratories today despite the important benefits that both laboratories would realize from such interfaces.

"The other basic source of LIS incompatibility derives from the fact that the three national laboratories still operate on an ASTM standard instead of HL-7," observed Tribbett. "This need for clinical integration is what spurs efforts to move toward common standards like HL-7 and LOINC (laboratory ordering information numeric code)."

Among the three blood brothers, **Quest Diagnostics Incorporated** is in the transition from ASTM version 94 to HL-7. SmithKline Beecham Clinical Laboratories is in the transition from ASTM version 88 to HL-7. At Laboratory Corporation of America, the transition must convert from ASTM version 92 to HL-7.

"This illustrates the wide variation in the basic structure of LIS software used even by the national laboratories," stated Tribbett. "Until most healthcare providers move to a software system based on a common HL-7 platform, one of the trickiest decisions facing laboratory administrators is how to upgrade their existing LIS and still be compatible with future changes and developments to software systems."

"When LabCorp joined Malden, we took LabCorp's test catalog and mapped it on top of existing data fields," he continued. "Physicians continued to order tests by the same name and received test results in the same format. Equally important, Malden and LabCorp received specimens and reported results using their existing systems without change or alteration.

"We solved another problem," added Tribbett, "which involved billing. Our software collects all the information necessary to prepare a consolidated bill. This information is forwarded to a third party billing service. We utilize a common patient identifier and pass along patient demographic data accompanied by CPT codes as provided by the ordering physician.

"The third party billing service is called **Coastway Corp.** and is part of The Malden Hospital organization," explained Tribbett. "It is an arrangement that Malden and LabCorp cleared in advance with HCFA, so it meets regulatory requirements governing billing and reimbursement practices."

Capabilities Illustrated

"The Malden Hospital project illustrates what capabilities our systems can deliver," observed Tribbett. "We can move data to outpatient/outreach order entry stations for five ancillary services: laboratory, radiology, cardiology, physical therapy and occupational therapy. We are able to capture 'medical records,' such as discharge summaries, operative reports, inpatient laboratory reports, inpatient radiology reports and move them to any appropriate physician or nursing home desktop computers."

Building from the first generation product used to initially link clinical services within The Malden Hospital system, Healthworks Alliance developed a "clearinghouse" concept with their technology. "The concept of the 'clearinghouse' is the easiest way to understand how we make it easy for users of our system to pass data," said Tribbett. "We create a master linking dictionary of laboratory tests. Applets (application software modules) create a registration screen which permits the physician's office to pull patient data from its office data base, incorporate it in the registration form and order services for that patient.

"This registration, or patient requisition, goes into the clearinghouse. There it is matched against the appropriate procedures which are in our master directory. The procedure is ordered and results are sent back to the physician."

What makes the clearinghouse unique is a distinctive feature: Healthworks Alliance can permit each

Tribbett Discusses LOINC's Potential

"Our system is already compliant with LOINC," said David Tribbett, Executive Vice President of Healthworks Alliance, Inc. "LOINC, which stands for 'laboratory information ordering numeric code,' promises to simplify how laboratory data is transmitted around the world by becoming the single standard.

"Unfortunately, few laboratory information systems are compliant," he continued. "It is something that the three national laboratories are diligently working towards. I believe that we are three to five years away from seeing LOINC become widespread.

"The challenge with making LOINC an effective tool is that it must eventually incorporate the business ordering rules affecting laboratory testing. By this I mean, what happens when a CBC is ordered? Although it is the same CBC, it is treated differently if it is ordered within the hospital, is an outreach test with private pay or is done for a Medicare patient. Right now the LOINC development teams are still working upwards from the simplest level of laboratory testing and have yet to tackle these more complicated issues."

user to continue to work from an established test catalog or requisition procedure. This eliminates the disruption to clients which is caused when the laboratory upgrades LIS software or makes major revisions to its test catalog.

"Probably the best way to describe the benefit of our clearinghouse function is this," elaborated Tribbett. "We can create an interface for the end user which never changes, regardless of how the laboratory changes test codes, switches reference ranges or alters the way testing is performed."

Clients Saw No Changes

"Let me give you an example. When Malden Hospital's laboratory switched from partnering with SmithKline to LabCorp, Malden's outreach clients saw no changes to ordering procedures, test catalogs or normal ranges. Our clearinghouse matched existing order procedures with the appropriate tests from either Malden or LabCorp.

"An even more extreme example is **Nazareth Hospital**, which has used our network system linking ancillary services with outpatient providers for seven years. A while back they were purchased by **Franciscan Health**. Franciscan used a different HIS and LIS than Nazareth and converted Nazareth to their IS platform. Then, two years ago, Franciscan Health was purchased by the **Catholic Health Initiative**. They had a different HIS and LIS than Franciscan. Again, Nazareth Hospital switched platforms.

"Through all these changes, the physicians, surgicenters and nursing homes were completely unaffected. They continued to register patients the same way, place orders the same way, and receive results the same way. There was no disruption or turmoil, even though the hospital changed HIS twice in a four-year period!"

These are impressive results for any information system vendor. Healthworks believes that it has refined this technology to the point where the company is ready to tackle the challenge of hospital-reference laboratory CPU-CPU links.

Healthworks Alliance is currently exploring how to develop a reference laboratory clearinghouse which would allow any reference laboratory to create a seamless data integration capability with their clients. Discussions are under way with the national laboratories and the leading reference laboratories.

"There are two major benefits that this reference laboratory clearinghouse offers both clients and reference laboratories," noted Tribbett. "First, the client and reference laboratory can be linked quickly and economically. This eliminates the $10-$50,000 cost and six-month to one-year wait for a custom interface to be written, tested and implemented.

"They continued to register patients the same way, place orders the same way, and receive results the same way. There was no disruption or turmoil even though the hospital changed HIS twice in a four-year period!"

"Second, the clearinghouse maintains a testing dictionary which handles updates and changes to the test catalog, procedures and reference changes by the reference laboratory. These changes are unnoticed by the client because the registration/order module remains constant.

"Further, the clearinghouse also maintains a cumulative charting capability. Even as a laboratory changes tests or reference ranges, we can report the cumulative test history of that patient in a consistent format. We do this by reporting the individual tests accompanied by the normal ranges effective on the date the test was performed.

Four "Components" Support Integration

"Currently we are implementing our third generation network product," noted Geri Beyer, Director, Corporate Accounts at Healthworks Alliance. "There are four components which permit us to maintain a constant entry and reporting process, regardless of changes to test catalog and other elements.

"The first component, or module, is 'Universal Order Entry.' Orders can be placed by any healthcare enterprise," she explained. "The second is 'Universal Results Reporting.' This obviously provides reports for all procedures which are performed.

"Module Three is 'Universal Registration.' This a unique part of our network system. It allows us to collect all the required financial and demographic information required to prepare an accurate and detailed bill.

"What is common to these three components is that the user sees and interacts with them," stated David Tribbett, Executive Vice President. "The fourth component is the glue which binds these applications. We call it the object broker. It communicates between all the applications. It uses a universal communications protocol and a plain-vanilla HL-7 standard. There are no z segments to be found.

"This permits us to offer a turnkey solution which can be dropped into the desktop or network at a clinic. Now they can register the patient, place orders and receive results from any provider within the integrated delivery system."

"Another feature of the clearinghouse is its capability to support accurate billing. For example, within an integrated delivery system, we maintain a unique patient registry. This permits the clearinghouse to track all clinical procedures done on the same patient, then deliver that data with the appropriate information to the reimbursement department. It improves the accuracy of reimbursement claims.

As a corporate strategy, Healthworks Alliance has accurately recognized the need for a simpler solution to clinical integration among various healthcare providers. In many respects, the solution developed by Healthworks Alliance also seems user-friendly. This uncommon benefit distinguishes it from the complicated information systems dominating the marketplace today.

Link Ancillary Services

In developing a way to economically and easily link ancillary services at the hospital with physicians in the community, Healthworks Alliance further realized something that all laboratorians have understood from day one: it is clinical laboratory data which is used most frequently and which has cumulative value over time.

Healthworks further recognized that the marketplace was already moving to integrate laboratory data ahead of any other service. This process began in the early 1990s as commercial laboratories began placing PC-based requisition and reporting systems into physician offices and linked them with the laboratory using a dedicated telephone line.

Parallel Dynamic

The parallel dynamic was under way between reference laboratories and their hospital laboratory clients. Creating the CPU-CPU link between reference laboratory and client has become a major service requirement.

Healthworks Alliance should get recognition for bringing early solutions for clinical data integration to the marketplace. If they can get their reference laboratory clearinghouse into operation in the near future, they may become the leading vendor for integrating laboratory information systems with integrated healthcare delivery systems. TDR

(For further information, contact Jack Darnell at 800-335-8346, ext. 111)

Lab Industry Briefs

MONOLAYER PAP SMEAR TEST

In travels to laboratories around the United States, THE DARK REPORT is getting interesting, but anecdotal, feedback about **Cytyc Corp.'s** ThinPrep® monolayer Pap smear test. Pathologists and laboratory directors are noticing two perceived benefits to using the ThinPrep process. One, their cytologists are able to report a higher percentage of Pap smears as positive or negative, without qualification. Two, because the cytologists are more definitive with their diagnosis of the Pap smear, fewer slides go to the pathologist for review.

The added cost of the ThinPrep Pap smear is an issue with laboratories. Despite that fact, laboratories using ThinPrep seem genuinely enthusiastic about the perceived benefits they are discovering. A new clinical study of the ThinPrep process was just published in the August issue of *Obstetrics & Gynecology*. It involved more than 7,000 patients. Lead author was Kenneth R. Lee, M.D. of **Brigham & Women's Hospital**, **Harvard Medical School**. Laboratory executives considering automated Pap smear technology will find some interesting conclusions in this new study.

NEW SHOTS FIRED IN PAP SMEAR WARS

Clients of THE DARK REPORT are aware that numerous lawsuits now plague the first three automated cytology companies to begin selling their products. Competition has already moved from the laboratory marketplace into the courtroom. Now it appears that the **Food and Drug Administration's** regulatory process will be used as a competitive tool. According to Cytyc president and CEO Patrick Sullivan, the FDA recently received petitions requesting administrative review of the pre-market approval application for Cytyc's ThinPrep system. Some of the petitions were filed by, or at the request of, Cytyc's competitors. Cytyc says that one of the petitions was filed by Carl Genberg, a director of **Neuromedical Systems, Inc.** and president of **Cytology West, Inc.**

CALIFORNIA BRACES FOR NEW LAWS AFFECTING MANAGED CARE

Laboratory executives should carefully watch developments in California over the next year. As the consequences of an advanced managed care environment become clear to consumers, legislators and providers, changes and reforms are expected.

Look for the state legislature to be the main battleground. Throughout the United States, over 1,000 managed care bills have been introduced since January 1997. In California, the senate has 50 healthcare bills to consider which were passed by the assembly. Meanwhile, the assembly has 30 healthcare bills to consider which passed the senate.

Because big dollars are involved, the fights will be intense. On one side, a coalition of labor unions, the **American Association of Retired Persons** and **Consumers Union** seek an 11-point "patient bill of rights." On the other side, the **California Medical Association** is backing laws to make it

more difficult for HMOs to drop physicians from their networks. Opposing all of this is the **California Association of Health Plans**, the managed care industry trade group.

The environment for clinical laboratories in California is already financially stressful. Managed care "reforms" passed by the legislature during the next 12 to 18 months could make it more difficult for laboratories to provide services and stay in business.

LABCORP TO USE AFFYMETRIX'S HIV ASSAY

One of the more interesting diagnostic technology companies is **Affymetrix, Inc.** of California. Affymetrix is striving to develop a variety of diagnostic testing chips which would perform laboratory tests in micro wells using minute quantities of reagents and specimens.

Although this technology is still under research, the company offers a number of diagnostic assays. **Laboratory Corporation of America** announced on August 5 that it will use Affymetrix's GeneChip® DNA probe arrays and PCR (polymerase chain reaction) based assays for HIV genotyping.

Although not a major agreement in terms of money or test volume, it is a way for LabCorp to develop a working relationship with Affymetrix. Should Affymetrix eventually succeed in developing its "micro testing chip" to be a high-quality, low-cost product, then LabCorp may have positioned itself to participate in clinical trials. It might also be the first to offer the resulting technology on a commercial basis. THE DARK REPORT expects to see all three of the national laboratories develop such relationships with diagnostic research companies.

LABONE, INC. POSTS STRONG EARNINGS

Lab*One*, Inc. performed well during the second quarter of 1997. The Lenexa, Kansas-based laboratory reported growth in each market segment of diagnostic testing it offers. Life insurance testing volume increased 24% over the previous year. Life insurance companies lowered the threshold for testing because of the reduced cost of using **Epitope's** OraSure® HIV saliva test. Clinical testing increased 124%. Substance abuse testing increased 123%.

Of particular interest is Lab*One*'s LabCard® program. Covered lives now exceed 1.3 million. Contracts covering another 450,000 lives await implementation. After three years of marketing, this program is beginning to take off.

Lab*One* is a good example of an independent laboratory which diversified its primary revenue base (life insurance testing) by developing specialized testing products for specific markets. Total revenues for second quarter increased from $14.8 million to $20.3 million over the same quarter last year. That growth rate is unmatched by most public laboratories during the same time period.

LABORATORY SPECIALISTS OF AMERICA GROWING

Another speciality laboratory which is performing well is **Laboratory Specialists of America**. This laboratory offers drugs of abuse testing and did several modest acquisitions during the last two years. Headquartered in Oklahoma City, the laboratory reported revenue growth of 42%, to $3.4 million during the first six months of this year. Net income increased 82%, to $622,000 in the same period. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Meris Laboratories continues to be a turnaround challenge. The company announced on August 4 that CEO and President Denis Simon had resigned. Appointed by the board on March 25, Simon stayed less than 18 weeks in the position. Like several other California labs, the San Jose-based company has struggled financially in recent years.

ADD TO:... CALIFORNIA LABORATORIES

Meanwhile, the state's largest laboratory, **Unilab, Inc.** got a boost. On August 7, **Standard & Poor's** revised its business outlook on Unilab from negative to stable. The bond rating company noted that Unilab had improved both operating margins and EBITA (earnings before interest, taxes, depreciation, and amortization) in recent months. Standard & Poor's continues to give Unilab's bonds a speculative rating due to the company's high leverage and the heavy penetration of managed care in the California marketplace.

Regional Sales Manager James Cameron from **Quest Diagnostics Incorporated's** Denver region noted that Quest's laboratory in Billings, Montana was not closing down completely. *(See TDR, June 23, 1997).* Cameron indicates that "time-sensitive" laboratory tests will continue to be performed at the Billings laboratory. Other specimens from that market will be sent to Quest's Denver facility for testing.

Check out the AACC's audioconference on *An Introduction To ISO 9002 Registration*. Scheduled for November 5, 1997, it is a basic overview as to why ISO 9002 is a management strategy worth considering. As laboratory executives seek to "reinvent" themselves to stay relevant with changes under way in healthcare, it becomes imperative to stay up with successful management models. Quality management programs such as ISO 9002 represent the new paradigm shift in healthcare management strategies.

HIGHER HMO PREMIUMS

Indications are that corporations will pay higher premiums for the next fiscal year. Compensation experts predict companies will pay an average of between 6% and 10% more. This reverses a trend of declining or flat premiums experienced in recent years. Clinical laboratories may see further reimbursement declines from private payers as they seek to preserve profit margins.

MORE ON:...PREMIUM INCREASES

One reason behind the widespread premium increases are disappointing profit margins at publicly traded managed care companies. "It must be very clear to everybody that the HMOs have to raise prices at least 5% or they are in big trouble," said Kenneth Abramowitz, healthcare analyst at **Sanford, Bernstein & Co.**

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 15, 1997

THE DARK REPORT

UPCOMING...

- *Strategies For Outreach Success: A Rural Hospital Lab Grabs Market Share.*
- *Close-Up Look At Financial Performance Of Large Commercial Laboratories.*
- *New Models For Laboratory Joint Ventures: Will They Succeed?*
- *Clinical Laboratory Automation: Modular Approach Is On The Fast Track.*