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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Laboratories Enter The Era Of Big Government

You will read in this issue of THE DARK REPORT how federal prosecutors have now taken all three of the national laboratories to the woodshed. **SmithKline Beecham Clinical Laboratories** was the latest to make the trip, paying $325 million to settle a wide variety of allegations and violations of Medicare regulations.

However, there is something more important than the news of SmithKline's huge settlement. Federal regulators are about to change virtually every aspect of how the clinical laboratory industry conducts business. In the process, they are going to make laboratory directors and managers personally liable for criminal charges should investigators decide that a laboratory did not correctly comply with new rules.

Clinical laboratory executives are about to learn a new management skill: government compliance. It will be expensive. It will be time consuming. In the foreseeable future, I expect HCFA to introduce a steady flow of guidelines, test panel revisions, national directives and similar initiatives. Laboratories will watch operating profits steadily shrink, as one motive in these efforts is to cut Medicare/Medicaid costs.

Although I am sympathetic to the plight of the industry, I must point out that none of the issues raised by Medicare/Medicaid officials seem to trouble private payers. This is the difference between the government and the private sector. As government regulators begin implementing a slew of new guidelines, regulations, model compliance programs and the like, clinical laboratories will groan under the burden of compliance.

These developments now bring laboratories into an age of big government. So long as they accept Medicare/Medicaid funding, they will have to play the government's game. Universities and colleges went through this as a result of accepting federal grants and other types of funding, the most recent examples of government influence being the introduction of females into **The Citadel** and **Virginia Military Institute**. Easy solutions to problems and common sense are not normally associated with government programs.

As the government prepares to go after 5,000 hospitals for alleged violations of laboratory billing regulations, small independent labs should be preparing for their own shakedown. Now that government investigators have acquired both knowledge and legal precedents in their investigations of the national laboratory chains, it would be foolish to think that they will ignore the 1,000 plus independent laboratories still in business around the country. **TDR**

SmithKline Announces $325 Million Settlement

Charges include billing practices through 1996 as well as violation of physician kickback statutes

CEO SUMMARY: Prosecutors continue to investigate. Criminal charges could be forthcoming against the company and individuals. Allegations against SmithKline expand the scope of laboratory practices that government regulators consider to be violations of existing statutes.

DESPITE THE FACT THAT **Smithkline Beecham's** settlement was expected, details of the case generated surprise among lab industry executives.

At $325 million, SmithKline's settlement is the largest amount paid by a clinical laboratory to date. It was public knowledge that the company had reserved that amount and expected to pay in excess of $300 million.

The announcement was made Monday, February 24, 1997. The SmithKline case is the latest settlement in what government prosecutors now call "Operation LabScam." It began when seven laboratories received subpoenas in August 1993.

Six of the laboratories under subpoena have signed settlements. Only **Nichols Institute**, now owned by **Quest Diagnostics Incorporated** (formerly **Corning Clinical Laboratories**) has yet to settle. That investigation continues. During the previous two years, Quest has increased reserves relating to the Nichols Institute subpoena.

Although the civil settlement closes this part of the SmithKline case, United States Attorney Michael Stiles stated that investigations continue and criminal charges could be forthcoming. Such criminal charges may involve the company, company officials and possibly physicians and other healthcare providers who were clients of **SmithKline Beecham Clinical Laboratories**.

THE DARK REPORT expects that criminal investigations and prosecutions will be pursued in the SmithKline case for two reasons. First, the government wants to send a message to the

entire healthcare industry. To follow up SmithKline's civil settlement with criminal charges would insure headlines throughout the country.

Second, federal prosecutors have two advantages in pressing criminal charges in the SmithKline case. Investigators and prosecutors now possess a sophisticated and extensive understanding about clinical laboratory marketing and business practices. This is the result of six years of investigatory efforts.

Also, evidence against SmithKline is both abundant and fresh. Allegations against the company include reimbursement claims and business practices dating through 1996. Unlike earlier settlements for unbundling activities prior to 1994, SmithKline's recent practices were at issue. With fresh evidence available, it makes it much easier for government prosecutors to assemble compelling criminal cases against their targets.

The precedent for criminal prosecution exists. In the 1992 settlement with **National Health Laboratories**, an executive pled guilty to criminal charges and served jail time. **Damon Laboratories** agreed to criminal charges last fall and it is known that former Damon employees in Boston were called to testify in front of the grand jury.

Criminal Charges

Prosecutors were attempting to develop criminal charges against several ex-Damon executives. But Damon was acquired by **MetPath** (now Quest) in 1993. Thus, by 1996 it was difficult for federal prosecutors to assemble sufficient evidence to obtain criminal indictments.

Should criminal indictments be issued in the SmithKline case, it will be a wake-up call to both the laboratory industry and their physician clients. Besides basic allegations of test unbundling common to virtually all of these settlements, SmithKline was

SmithKline Lab Case Involves Six Issues

Alleged false claims submitted from 1989 through 1996 by SmithKline Beecham Clinical Laboratories were at issue in the settlement with federal investigators. Charges centered around these six issues:

- **Test Unbundling:** add-on tests neither ordered nor needed by physicians.
- **Tests Not Performed:** relating to issues of specimen integrity, insufficient quality and similar problems.
- **Add-On Indices:** such as hemagram indices added to CBCs.
- **Double Billing:** involving kidney dialysis tests where covered by composite rates. Also issues of medical necessity or use for diagnostic purposes.
- **Inducements/Kickbacks**: at issue was free equipment, such as computers and faxes, phlebotomists employed by SBCL in doctor's office, payment of "lease/rent" and testing provided either free or below cost to physician and staff as "medical courtesy."
- **Code Jamming:** new term for federal regulators. Describes the practice of a laboratory providing ICD-9 (diagnostic) codes for screening tests.

alleged to have induced business from physician clients.

This raises the stakes for all clinical laboratory executives responsible for administering billing and reimbursement practices. SmithKline is alleged to have provided physician clients with free computers, fax machines, refrigerators and similar equipment and supplies.

Wherever these items were not used exclusively by the physician for outside laboratory functions, federal prosecutors viewed this as an inducement or kickback. Also at issue was the practice of SmithKline placing a phlebotomist in physicians' offices and paying some type of "lease" or "rent" arrangement to the doctors.

Other Labs At Risk

Because clinical laboratories throughout the United States commonly provide computers, faxes, and phlebotomists to physician clients, the government's actions against SmithKline regarding these issues may make all laboratories vulnerable to civil and criminal settlements based upon these issues.

The risk may be greatest in California. Last year the **California Clinical Laboratory Association** (CCLA) notified all licensed laboratories in the state that placing phlebotomists in the physicians' offices violates existing state statutes. Should federal prosecutors choose to enforce similar federal statutes, California laboratories may find themselves facing investigation by both state and federal prosecutors.

With the added threat of criminal prosecution, clinical laboratory executives will need to seriously consider the consequences of continuing these practices, regardless of what competing laboratories may choose to do.

The case made by government prosecutors against SmithKline Beecham Clinical Laboratories is important. It represents the current thinking of federal investigators and prosecutors in their efforts to curtail Medicare/Medicaid fraud and abuse by clinical laboratories.

This case establishes a number of precedents. It creates new issues and concerns for clinical laboratory executives. Should criminal charges be forthcoming against SmithKline officials, expect that government prosecutors will use their SmithKline experience as a template against other clinical laboratories.

SmithKline's public statements do little more than reflect the popular defense that, as stated by SmithKline CEO Jan Leschly, "Part of the problem, not just for SmithKline, but for the entire industry, lies in ambiguities over regulations and guidelines." But that does not address issues such as billing for tests not performed. Guidelines on this point are clear and definitive.

Many details of this settlement are relevant for the entire laboratory industry. It provides specific documentation about how the government is interpreting and enforcing statutes and guidelines governing clinical laboratory activities for federal healthcare programs.

New Compliance Program

Federal regulators chose the occasion of the SmithKline announcement to introduce a national compliance program *(see page 5)*. This is a further sign to the laboratory industry that enforcement of regulations and statutes will continue.

Expect more investigations to be announced, as investigators begin probing regional independent laboratories and hospital-based laboratories. **TDR**

(For further information, contact THE DARK REPORT at 800-560-6363.)

Government Regulators Transforming Lab Industry

New compliance guidelines for laboratories represent watershed change for the industry

CEO SUMMARY: Medicare/Medicaid regulators get serious about laboratory billing and reimbursement practices. Industry observers say it represents a major shift and will have immense financial and operational impact on every clinical laboratory in the United States.

FOLLOWING YEARS of "benign neglect" toward Medicare billing practices, regulators will now scrutinize laboratory reimbursement activities with full vigor.

During the press conference announcing the $325 million settlement with **SmithKline Beecham Clinical Laboratories** on February 24, government officials unveiled a model compliance program for clinical laboratories.

Deliberately timed to coincide with the SmithKline announcement, June Gibbs Brown, Inspector General for **Health and Human Services,** introduced the model compliance program as an effort toward "promoting a high level of ethical and lawful corporate conduct and preventing future scams."

The model compliance program is a consequence of the ongoing investigation of laboratory industry practices. It represents a watershed change in how federal regulators will interact with clinical laboratories and the healthcare industry in general.

"This will be one of the most challenging times in the laboratory world," declared Dennis Weissman, Publisher of the *National Intelligence Report* in Washington, D.C. "The events now unfolding represent some of the greatest changes to laboratory practices since the introduction of DRGs in the early 1980s."

"The model compliance guidelines place new responsibilities on clinical laboratories which have never before existed," warned Weissman.

Weissman's comments were made in a speech at the **American Hospital Association's** annual laboratory conference held last week in Las Vegas. Weissman described how the regulatory climate toward clinical laboratories is undergoing radical change. These fundamental shifts will have far-reaching impact on how both hospital-based and commercial laboratories operate.

"The model compliance guidelines place new responsibilities on clinical laboratories which have never before existed," warned Weissman. "The guidelines make corporate managers

Model Compliance Guidelines For Labs

Here are 11 elements which federal regulators recommend be part of every laboratory's internal compliance program:

1. **Written standards of conduct for employees.**
2. **Development and distribution of written policies addressing specific areas of potential fraud.**
3. **Designation of a Chief Compliance Officer within the organization who is charged with operating the compliance program.**
4. **Development and offering of education and training programs for all employees.**
5. **Use of audits or other evaluation techniques to monitor compliance.**
6. **Development of a code defining improper or illegal activities and use of disciplinary procedures to enforce that code.**
7. **Investigation and remediation of identified systemic and personnel problems.**
8. **Promotion of and adherence to compliance as an element in evaluating supervisors and managers.**
9. **Development of policies addressing the non-employment or retention of sanctioned individuals.**
10. **Maintenance of a hotline to receive complaints and the adoption of procedures to protect the anonymity of complainants.**
11. **Adoption of requirements applicable to record creation and retention.**

accountable and responsible for the activities of their laboratory."

Wiessman advised that laboratory managers should give these new developments full and serious attention. Because Weissman has 20 years experience in advising the laboratory industry on regulatory and other issues, his opinions carry both credibility and authority.

As regulators introduce new guidelines and management practices into the laboratory industry, laboratory administrators and managers must respond appropriately. Failure to do so can be costly. Federal investigators will now hold managers personally accountable for how laws and regulations were enforced by individual laboratories.

Federal Regulators

Most of the laboratory industry is not aware that federal regulators have quietly taken a greater role in the day-to-day management of the larger commercial laboratories. Within those laboratories, a higher standard of compliance and management accountability is already in place.

Starting in March 1995, **Allied Clinical Laboratories** was the first company to sign a compliance agreement with the federal government. Since that date, five other laboratories have also signed compliance agreements.

They are **Quest Diagnostics Incorporated**, **Laboratory Corporation of America**, **Spectra Laboratories**, **Meris Laboratories** and SmithKline Beecham Clinical Laboratories.

These compliance agreements resulted from federal investigations. They were part of the resulting settlement conditions. For a term of five years, the laboratories agree to perform annual reviews of their compliance activities, certify that they are in compliance and report and disclose the results of such reviews and internal audits to the federal government.

Federal regulators call these "corporate integrity agreements." Some laboratories have released statements touting their new corporate integrity agreements as a positive step in compliance. In reality, federal regulators required the companies to execute these agreements in order to resolve outstanding allegations of Medicare fraud.

Enforcement Activity

Taken collectively, the actions of federal regulators in obtaining corporate integrity agreements and issuing model compliance guidelines to the laboratory industry demonstrate that enforcement activity will continue.

The broad extent of regulatory influence on laboratory practices will become apparent as further guidelines affecting billing, reimbursement and medical necessity are announced during the next 24 months.

Weissman discussed several of these initiatives during his speech in Las Vegas. He also provided a list of common laboratory billing infractions. Expect regulators to closely scrutinize eight specific areas as follows.

Unprovided Services

One, billing for unprovided services. Both Quest and SmithKline settled charges that they had billed Medicare for tests not performed or reported.

Two, misrepresenting a patient's diagnosis to justify services performed. One example of this would be if a laboratory does not get a diagnosis code from the physician, but provides one that was used for an earlier test by the same patient.

Three, deliberately billing multiple payers for the same test.

Four, unbundling or "exploding" charges. This is one area of federal investigation which will rapidly expand outside the laboratory and into hospitals and physicians' offices.

Five, misrepresenting the services rendered, the amounts charged for the services rendered, the identity of the person who received the services, or the dates on which the service was performed.

Six, billing for uncovered services.

Seven, participating in schemes that involve collusion between providers or suppliers that result in higher charges to Medicare.

Eight, utilizing split billing schemes.

The government is providing extensive information about regulatory issues on an internet site. The site is maintained by Human Health Services and the Office of the Inspector General. It can be reached through the internet address of http://www.sba.gov/ignet/internal/hhs/hhs/html. TDR

(For further information, contact Dennis Weissman at Washington G-2 Reports, 202-789-4062.)

Six Laboratories Signed Corporate Integrity Pacts

As part of the settlement of allegations of Medicare fraud, six clinical laboratories signed and implemented corporate integrity agreements with the federal government:

Allied Clinical Laboratories.
March 20, 1995

Corning Clinical Laboratories
(Now Quest Diagnostics Inc.)
October 9, 1996

Laboratory Corporation of America
November 20, 1996

Spectra Laboratories
December 10, 1996

Meris Laboratories
February 12, 1997

SmithKline Beecham Clinical Labs
February 24, 1997

Whistleblowers Play Big Role In SmithKline Laboratory Case

WHISTLEBLOWERS PLAYED A SIGNIFICANT ROLE in the recent settlement between the federal government and SmithKline Beecham Clinical Laboratories (SBCL). At least seven different whistleblowers filed suit against SBCL and will share in the settlement. Federal statutes permit judges to award up to 25% of the settlement to whistleblowers. This means whistleblowers could split as much as $81 million of the $325 million settlement. A ruling on this phase of the lawsuit is expected shortly.

The major whistleblower was Robert Morena. He worked in data and systems management at SmithKline's national billing center in Collegeville, Pennsylvania. Public records indicate that when Morena noticed billing problems four years ago, SmithKline executives ignored his requests that billing irregularities be addressed and solved. After filing his suit almost three years ago, Merena assisted federal investigators in understanding subpoenaed documents and how billing processes worked at the billion-dollar laboratory. He resigned his $50,000 per year position with the company as part of a negotiated settlement of his *qui tam* lawsuit.

The medical director of SmithKline's laboratory in San Antonio, Texas was another whistleblower. Charles W. Robinson, M.D. raised questions about both marketing and billing practices. According to his attorney, John Clark, Dr. Robinson was told, "Thanks for telling us, but we know what we are doing." He resigned his job in 1993 and filed his whistleblower lawsuit that same year.

The original laboratory industry whistleblower, Jack Dowden, had also filed suit. Dowden was the individual who launched the **National Health Laboratories** case. He and Kevin Spear filed an action against SmithKline and will share in the settlement. Other whistleblowers who will share in the settlement between the federal government and SmithKline are Glenn Grossenbacher, a San Antonio attorney; Jeffrey S. Clausen of Gwinnett County, Georgia; and William St. John LaCorte, M.D. of New Orleans, Louisiana.

With the federal government tightening compliance requirements for clinical laboratories, THE DARK REPORT expects to see more whistleblower actions. These would be originated by employees in smaller regional labs and inside hospital-based laboratories. For that reason, it is recommended that laboratory executives act swiftly to perform legal due diligence. Timely actions to insure that the laboratory is in full compliance can forestall both whistleblower lawsuits and federal investigations.

Managed Care

Cigna Buys HealthSource, Inc., Increases Managed Care Clout

CEO SUMMARY: Consolidation continues among managed care companies. Cigna's acquisition is an effort to boost its managed care business. Healthsource's market coverage complements areas where Cigna can use the additional market strength to negotiate more favorable contracts with providers.

HEALTHCARE CONSOLIDATION continues with **Cigna Corp.'s** agreement to purchase **Healthsource, Inc.** for $1.4 billion. The acquisition will boost Cigna's managed care lives to 3.16 million and fee-for-service lives to almost 9 million.

Cigna's action is driven by the need to gain a critical mass of lives, particularly in regions where it does not have enough enrollees to negotiate aggressive discounts from physicians and other providers.

For clinical laboratories, consolidation among national managed care companies is a sign that these companies are having difficulty competing with integrated delivery systems in some localities. Last year **Aetna** purchased **U.S. Healthcare** because it needed additional expertise to organize HMOs throughout the United States as quickly as possible.

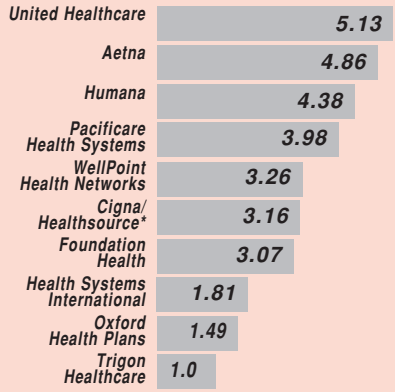
Cigna's acquisition of Healthsource will not be trouble-free. Healthsource reported poor earnings during the fourth quarter of 1996. It was created by a group of doctors in 1985 to provide HMO services primarily to smaller cities and rural areas. Healthsource grew quickly through acquisitions. But as prices tightened and costs increased, management had difficulty maintaining profitability.

Cigna will not only have to integrate Healthsource into the company, but it will also have to successfully manage Healthsource's problems. That will tax the management team at Cigna. It may provide an opportunity for local competitors who are nimble to gain market share at Cigna's expense.

Expect other mergers among managed care companies. The chart below illustrates the disparity between **United Healthcare**, **Aetna** and **Humana** at the top, and those managed care companies further down the list. **TDR**

Managed Care's Top Ten

Here are the largest ten managed care health plans of publicly traded companies, ranked by millions of members.



*Cigna alone: 2.17 million, seventh place. HealthSource alone: 986,000, 11th place.

Note: All figures from 12/31/96.
Source: Sherlock Co.

Las Vegas Lab Gathering Debates Industry Trends

Annual American Hospital Association laboratory meeting uncovers hot topics

CEO SUMMARY: Always a good forum for discussion of laboratory industry trends, this year's meeting in Las Vegas addressed government regulation, laboratory automation and everything in between. Here is a brief rundown on some of the more interesting insights and observations.

ONLY A LIMITED NUMBER of laboratory programs exist which address the management interests of hospital laboratory directors and administrators. One such important gathering is the **American Hospital Association's** annual laboratory conference.

Held on March 6-7 in Las Vegas, almost 300 laboratory directors assembled to hear 21 presentations on the entire range of laboratory management issues. Some of the information was worthwhile and of interest to DARK REPORT clients and subscribers.

Relevant Insights

What you will read in the following pages are relevant insights which seem to accurately illustrate problems and solutions of common interest to proactive laboratory managers. This knowledge should be useful to you and your laboratory organization.

The AHA program had a working title of *Integrated Health Care Strategies For Health Systems and Hospital Laboratories*. David A. Anderson was the keynote speaker who opened the conference. He is a founding partner of **Health Care Futures** in Itasca, Illinois.

While employed by **KPMG Peat Marwick**, Anderson and Dr. Stephen Shortell of **Northwestern University** conducted a joint research project. The goal was to identify what key relationships were essential for clinical integration. They co-authored a book on their findings.

Credible Research

Anderson's research is credible because it is based on the experience of eleven respected healthcare systems throughout the United States. *(See map and sidebar on page 11.)*

Basically, Anderson and Shortell determined that success in the managed healthcare world depends on clinical integration. "As we created diagrams of the key relationships within an integrated system," stated Anderson, "we identified clinical relationships which were common to the successful systems. We found these relationships to be statistically significant.

"We discovered that, to create value, the real key is to achieve clinical integration, not operational integration," he explained. "We know from our study that you cannot start from operational integration."

Health Systems Surveyed By Northwestern University

These are the eleven hospital systems surveyed as part of the Northwestern University/KPMG Peat Marwick research study of clinical integration.

Sisters of Providence

Fairview Hospital and Healthcare Services

Henry Ford Health Services

Mercy Health Services

Sutter Health

Advocate Health Care

Franciscan Health System

UniHealth America

Sentara Health System

Sharp Healthcare

Baylor Health Care System

Research study results published as Remaking Health Care In America: Building Organized Delivery Systems. *Authored by David A. Anderson and Dr. Stephen M. Shortell*

Anderson offered several conclusions from the study. First, larger hospitals that create common pathways will end up with clinical integration. Second, larger hospitals that integrate data tend to have more clinical integration.

"It is a fact that organizations which grow one hospital at a time have a greater struggle to accomplish clinical integration," said Anderson. "This is because they tend to maintain the status quo. Mergers of hospitals tend to expedite clinical integration because there are timetables to bring the different institutions together."

Anderson described four barriers to clinical integration within a healthcare system. First, there are strategic barriers. The system must focus activities on strategically important issues facing the system. "Without strategic integration," stated Anderson, "you tend to spend time on initiatives which do not serve strategic goals."

Second, structural barriers must be identified. The overall organizational structure of task forces, committees, councils and work groups must be directed to foster clinical integration and best practices. "If the structural barriers are still in place," he continued, "then efforts toward true clinical integration become isolated events."

Third, cultural barriers consist of underlying beliefs, values, norms and behaviors within the system. "Too often

an organization relies on a champion," Anderson explained. "When the champion loses steam or leaves, things stop unless the organization's culture reinforces the goal of clinical integration."

Fourth, technical barriers should be overcome by providing the necessary tools, training and skills to achieve clinical integration. "Without providing the technical support," he observed, "it becomes difficult if not impossible to move the organization forward."

Anderson stated that, during the last 30 years, the healthcare system in the United States has responded to two basic trends. "One was adapting to new healthcare technology. The second was responding to Medicare and its influence on healthcare practices."

According to Anderson, aging baby boomers will not be the next major trend to shape healthcare. He predicts something different. "The most dramatic factor to which healthcare must respond is the growing ethnic diversity of the population. For example, in four years hispanics will become the largest component of Chicago's population. California is already multicultural. These distinct cultural groups will require healthcare services which are sensitive to their lifestyles and cultural norms."

High Cost of Hospital Beds

Anderson closed his remarks by noting the following statistic: the cost per hospital bed in the United States is $170,000. That is 62% higher than the next highest country—Canada!

"The question is this: Can an organized healthcare system respond to managed care?" asked Anderson. "Our research says that healthcare systems do have the capability to accomplish this. As they achieve clinical integration, they will become the vehicle to link the community with these forces."

A presentation made later on the same day by Bruce Friedman, M.D. on *Laboratory Information Technology: Organization Integration* echoed the themes presented by David Anderson. Dr. Friedman, who is Professor of Pathology at the **University of Michigan**, pointed out that the healthcare industry uses the word "virtual" to describe organizational initiatives which do not involve a merger of assets.

Need To Integrate Data

"With hospitals seeking consolidation of their laboratories and the need to integrate data," observed Dr. Friedman, "I believe that we will see the emergence of the true 'virtual laboratory.' This will be the only organizational form that is fluid enough to adapt to changes in the organization, new testing technology and the evolving demand for healthcare services."

According to Anderson, aging baby boomers will not be the next trend to shape healthcare. He predicts something different.

Contrary to the paradigm, Dr. Friedman believes that both the laboratory professional and the clinician are prepared for the "virtual laboratory." "This concept is not a radical shift in thinking," he explained. "Laboratories already have a history of outsourcing reference and esoteric testing.

"New testing technology will bring rapid changes to the capability of laboratories. Regardless of the aliases such as POCT and AST, the common theme is the telescoping of testing from the analytic phase into the pre-analytic phase.

"As the laboratory diffuses into testing nodes spread throughout the integrated system," continued Dr. Friedman, "information technology is

Demand For Hospital Beds Indicates Excess Capacity

During Barry Portugal's presentation, he showed this slide. Projected demand for hospital beds is less than half of current capacity. (Portugal is President of Health Care Development Services, Inc.)

Even more interesting is the fact that most western and southern cities have almost half the beds per 1,000 population as cities in the east and midwest. But projected demand for all market areas is about half of existing capacity in those markets.

Market	1994 Staffed Beds*	1996 Need*	Est. Demand 100% M.C.*
Boston	6.1	3.2	1.6
Pittsburgh	6.0	3.8	1.9
New York	5.5	3.3	1.6
Cleveland	5.4	2.5	1.7
Tampa	5.1	2.7	2.2
Philadelphia	5.0	3.2	1.6
St Louis	5.0	2.4	1.6
Miami	5.0	2.3	1.8
Chicago	4.3	2.2	1.5
Houston	4.3	2.0	1.3
Detroit	4.0	2.3	1.5
San Francisco	4.0	1.6	1.4
Los Angeles	3.7	1.5	1.3
Dallas	3.6	2.0	1.4
Atlanta	3.5	2.1	1.4
Phoenix	3.2	1.6	1.5
Minneapolis	2.8	1.8	1.5
San Diego	2.8	1.5	1.3
Seattle	2.5	1.5	1.4
AVERAGE	**4.3**	**2.3**	**1.6**

*** Beds Per 1,000 Population**

Source: The Sachs Group, *Hospitals and Healthcare Networks*, January 1996

the enabler for the virtual laboratory. But this will not evolve without the notion of strategic direction."

Dr. Friedman's reference to strategic direction dovetails precisely with David Anderson's study conclusions. His prediction is that lab information systems will be essential in expediting clinical integration within a healthcare system.

Lab Automation

Laboratory automation guru Rodney S. Markin, M.D., Ph.D. discussed current developments in laboratory automation. Dr. Markin developed a line of automation equipment at the **University of Nebraska Medical Center**, where he is Professor and Vice Chairman of the Department of Pathology and Microbiology.

Dr. Markin noted that there are four prime vendors for automation equipment: **Autolab**, **BMC/Hitachi**, **Coulter/IDS** and **LAB-InterLink**. Among them are 13 laboratory sites in the United States and Canada where this equipment is either operating or under installation. This compares with Japan, where 141 laboratory sites are using automated equipment.

Four Vendors

The four vendors mentioned above have developed complete transport and automation solutions. "Instrument manufacturers are beginning to deliver instruments with varying capabilities for connecting to automated transport lines," said Dr. Markin. "**Johnson & Johnson's** 950AT and 250AT offer connectivity through both hardware and software. **Bayer**, **Chiron**, **MLA**, **Coulter** and **Dade** each have instruments with the capability to work within automated laboratory systems.

Workcell instrumentation is another form of automation. "More laboratories can benefit from this type of equipment, since smaller volumes of specimens make this equipment cost-effective," he explained. "There are four vendors with workcell solutions already in the marketplace. The firms are Johnson & Johnson Clinical Diagnostics, BMC/Hitachi, **Sysmex** and Coulter/IDS. Workcells can ini-

tially be used in modules. They can be later expanded as the laboratory installs automated transport lines."

Dr. Markin did not speak about the economics of automated systems currently installed and operating. There is little published data from which to judge the financial performance of this technology in actual use.

During the two-day program, attendees seemed upbeat. They were almost exclusively from hospital-based laboratories. The general impression was that they were holding their own against both managed care and commercial laboratory competitors.

Another surprise was that most of the hospital laboratory directors I spoke with who operated outreach sales programs indicated that they were doing well. Although there is a tendency to overstate success at such meetings, these laboratory directors could provide numbers and statistics to illustrate the growth of their outreach testing volumes.

The consistent theme which underlay most speeches as well as the conversations during breaks was that of consolidation and integration. Currently 77% of the hospitals in the United States have common ownership or an affiliation.

This is why consolidation and integration is widespread. Laboratory administrators are being asked to combine their laboratory operations with those of the affiliated hospitals.

Shift to Outpatient

At the same time, hospitals are trying to adapt to the shift from inpatient to outpatient. They are seeking ways to link every aspect of clinical services. Throughout this entire process there is an emphasis on cost savings.

Another notable fact about this gathering is that there were few attendees from commercial laboratories. Despite the fact that the big three national laboratories are promoting outsourcing and joint ventures, only the **Nichols Institute Division** of **Quest Diagnostics** was present with a display. It will be difficult to forge such relationships if the commercial laboratories do not interact with hospital laboratory directors at these gatherings. **TDR**

(For further information, contact Robert Michel at 503-699-0616.)

Independent Laboratories Market Share, 1989 and 1995

1989		1995	
SmithKline Beecham	15%	SmithKline Beecham	15%
Roche Biomedical	9%	LabCorp	21%
National Health Labs	8%		
Corning/MetPath	7%	Corning/Quest	21%
Damon Clinical Labs	3%		
Nichols Institute	2%		
Unilab	1%	Unilab	2%
Allied Clinical Labs	1%		
All Major Labs	46%	All Major Labs	59%

This slide was presented by Ann Meadow, Sc.D. of the Health Care Financing Administration, Office of Research and Demonstrations, Baltimore, MD.

The Dark Index

LabCorp Seeks $500 Million Through Public Stock Offering

CEO SUMMARY: After a financially difficult year in 1996, LabCorp enters 1997 with plans to raise $500 million. Despite the laboratory industry's poor prospects, LabCorp will probably succeed in raising capital. After this infusion of capital, will LabCorp's new management team have winning strategies that restore LabCorp to profitability?

IMAGINE ASKING WALL STREET for $500 million after the price of your stock plummets from $14 per share to under $4 in just 18 months!

Laboratory Corporation of America is doing exactly that. Company officials announced on February 27 that they were filing a registration statement with the **Securities and Exchange Commission** (SEC) and were preparing to raise $500 million.

In every large metropolitan area of the United States, laboratories are undergoing an unprecedented financial squeeze from managed care plans and other healthcare providers.

Credit Suisse First Boston Corporation will act as the dealer manager for this offering. The proposed offering consists of two series of convertible preferred stock.

In seeking to raise this money, LabCorp is using a bad news/good news approach for prospective investors. The bad news is that the integration between **Roche Biomedical** and **National Health Laboratories** took longer than anticipated. Medicare reimbursement cuts and increased managed care volume eroded profit margins. The settlement of Medicare fraud charges for $189 million was another untimely event.

In contrast, LabCorp can tell investors good news: all these bad things are resolved. The future is bright with a new CEO and management team.

Laboratory executives know this flies in the face of personal experience. In every large metropolitan area of the United States, laboratories are undergoing an unprecedented financial squeeze from managed care plans and other healthcare providers.

Changes in the way Medicare and Medicaid operate will further increase the financial stress on clinical laboratories. Not only will Medicare step up investigations of laboratory billing practices, but Medicare officials are busily rewriting test reimbursement guidelines, creating definitions of medical necessity and revamping acceptable test panels.

The result of all of this will be lower reimbursement to laboratories in tandem with increased costs to comply.

On the Medicaid front, the news is equally grim for laboratories. State after state is applying for federal

waivers to create Medicaid HMOs and similar health plans for their beneficiaries. These new healthcare plans replace the former fee-for-service Medicaid reimbursement with highly discounted or capitated fees. Laboratories experience declining reimbursement levels as a result of these Medicare reforms.

Viable Business Strategy

It is into this environment that LabCorp will attempt to do what no commercial laboratory has yet accomplished: find a viable, profitable business strategy. It is for these reasons that LabCorp's effort to raise $500 million surprises laboratory executives. It is not that LabCorp wants the money, it is that investors will ignore the experience of the last three years and fund the offering.

Corning/MetPath, Physicians Clinical Laboratories, UniLab and **Meris Laboratories** are all examples of successful laboratory operations which lost their luster in recent years.

Only 11 months ago, Unilab raised over $120 million through a corporate debt offering. By January 1997, all the original bondholders had sold their stake at a discount. Wall Street money managers got an expensive lesson in the economics of clinical laboratories.

A reading of LabCorp's 1996 year-end financial statement also highlights a key question. LabCorp touts the fact that they have produced $30 million more in savings than the pre-merger expectations of $80-$90 million per year.

This is a notable accomplishment, but competing laboratory executives understand an important consequence of this degree of cost-cutting: declines in service. Much of the savings generated by the commercial laboratories in their cost-cutting programs originates from two sources: staffing cutbacks and closing laboratory sites.

Each time a staff reduction takes place, beside the morale issue, there remain fewer people left to do the work. Inevitably there is work that goes undone. Clients cannot access services with the same ease as before the cutbacks.

New Executives At LabCorp And NeoPath

Laboratory Corporation of America's new chief executive officer wasted no time in restructuring his management team. Thomas P. Mac Mahon announced new appointments this month.

Richard L. Novak has joined LabCorp as the Executive Vice President, Eastern Operations. In that role he will handle LabCorp's Mid-Atlantic, Northeast, South and South Atlantic Divisions.

Novak spent ten years with **SmithKline Beecham Clinical Laboratories**. His positions there included Senior Vice President, U.S. Operations and President, International. Because of his background, he may make some interesting contributions to LabCorp's operations.

LabCorp's other executive change is the assignment of Larry L. Leonard, Ph.D. as Executive Vice President, Western Operations. In this role he will oversee LabCorp's Central, Great Lakes, Midlands, Southwest and West divisions.

Seattle-based **NeoPath, Inc.** announced the appointment of a new Chief Financial Officer. William C. Scott joined the company from **Boston Scientific Corporation**, where he was Vice President and General Manager of the **NW Technology Center** (formerly **Heart Technology**). Scott also is a member of the Board of Directors for the **American Heart Association's** Washington affiliate.

From an economic perspective, closing laboratory sites makes good sense and in theory should not result in any discernable decline in turnaround time or service. But the reality is that service does suffer. More nimble regional competitors rush to fill the vacuum and steal significant chunks of business.

That is LabCorp's Scylla and Charybdis. On one hand, they must develop a strategy to grow the business in a healthcare marketplace that is shrinking. On the other hand, they must cut costs in order to maintain operating profits. But in so doing they reduce service levels and make themselves vulnerable to regional laboratory competitors.

Of the three national laboratories, currently LabCorp is under the greatest financial pressure. Quest Diagnostics Incorporated (formerly Corning Clinical Laboratories) was able to reconfigure its balance sheet as part of the spin-off from parent **Corning Incorporated.**

SmithKline Beecham Clinical Laboratories (SBCL) has produced regular operating profits during the past year. Despite the expense of the federal settlement, SBCL finances are in better shape than those of LabCorp.

LabCorp's options are few. In order to keep its lenders happy, it must raise the $500 million. However, once the money has been obtained, the hard work begins. LabCorp's executive team must develop a business strategy that succeeds. To date, that is an accomplishment which has eluded the publicly traded commercial laboratories. Should LabCorp come up with the winning formula, they deserve the resulting success. **TDR**

Universal Standard Med Laboratories Announces 1996 Year End Financials

Universal Standard Medical Laboratories *(USML) of Southfield, Michigan released year-end earnings. Because of the laboratory's unique managed care programs, it provides valuable insights into marketplace trends.*

USML's 1996 revenues were $57.6 million compared to $66.5 million in 1995. Net loss for 1996 was $7.8 million compared to 1995's net loss of $1.0 million. The company took special charges in both years.

What is interesting is the impact which managed care is having upon the laboratory. During 1996, USML saw fee-for-service patient visits decline 14%. The company attributes this to several factors, including a shift of some patients to managed care programs, its own reduction in testing facilities and lost accounts. USML reports that fee-for-service revenue declined 17% as a result of these factors.

To offset these trends, USML has downsized and reengineered its central laboratory. CEO Eugene Jennings revealed that operating costs have been reduced by $6 million per year through these efforts.

USML operates a managed care division called ***Universal Standard Managed Care*** *(USMC). It provides services to 800,000 lives in all 50 states, but is primarily structured around major automobile manufacturers in the State of Michigan.*

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

The field of automated cytology is advancing quickly. Technology is rapidly pushing into the marketplace. Here's a sampling of recent developments among cytology-based companies…

Cytyc Corporation and **Laboratory Corporation of America** announced on March 6 that a national contract had been signed between the two companies. LabCorp will make Cytyc's ThinPrep® Pap smear available to physicians throughout the country.

MORE ON: Cytyc...
The company's Premarket Approval Application (PMA) Supplement was approved last month by the FDA to allow the use of the endocervical brush and plastic spatula for collection with the ThinPrep system. This will make it easier for Cytyc to get physicians to use ThinPrep, as these collection devices are in common usage.

NeoPath, Inc. was granted four additional patents used in its AutoPap® technology. The company now has 18 U.S. patents issued or allowed, with 25 patents pending.

Neuromedical Systems, Inc. released results of a new study. At the annual meeting of the United States and Canada **Academy of Pathology**, it was reported that Neuromedical's PapNet® System was able to detect cancerous and precancerous cells of the esophagus on conventionally prepared slides. In a study done by Leopold G. Koss, M.D. of **Montefiore Medical Center** in New York, 138 esophageal smears were reviewed. PapNet correctly identified all 36 patients who were positive or suspicious of cancer. The system also diagnosed two additional patients not previously considered diagnostic.

ACCUMED, INC. SHIPS PRODUCT TO EUROPE

AccuMed, Inc. has begun shipping its AcCell® and TracCell® systems to Europe under a contract with **Leica Microscopy and Systems GmbH**. Leica will distribute Accumed's products in Europe. AccuMed is the latest of the automated cytology companies to actively develop overseas markets for its products.

ELIMINATE INSTRUMENTS

Smart laboratory administrators should take the time to look at **Roche Diagnostic Systems'** new instrument, the COBAS Integra. It is a multi-test, random access machine capable of 72 different tests. One commercial lab manager told THE DARK REPORT that he was able to eliminate 17 instruments in his lab by consolidating specimen flow around the Integra.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 31, 1997

THE DARK REPORT

UPCOMING...

- *Next Installment: A Look At Laboratory Automation In Operation.*
- *Consolidated Hospital Laboratory Succeeds With Outreach In Tough Market.*
- *New Instrument Technology Which Expedites Laboratory Reengineering.*
- *Details Of THE DARK REPORT'S Upcoming Executive War College In New Orleans.*