From the Desk of R. Lewis Dark...



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

R. Lewis Dark: Gloom And Doom Versus Optimism	.Page	1
United Healthcare's Big Losses Derail Merger With Humana	.Page	2
"Corporatized" Healthcare Encountering Big Losses	Page	4
AACC Convention Exhibits Point To New Lab Trends	Page	7
Blunt Talk From HMO Blue's Ancillary Contracts Manager	Page	9
Laboratory Briefs: AccuMed, AutoCyte, Cytyc, MorphoMetrix, Neuromedical, NeoPath	Page	15
Intelligence: Late-Breaking Lab News	Page	18





Doom And Gloom Versus Optimism

COUNT ME AS ONE WHO IS NOT SURPRISED THAT SEVERAL of healthcare's billion-dollar corporations have posted huge losses. I may be at the age of retirement, and I might be guilty of values and ethics often labeled as "old fashioned," but I am possessed with common sense.

Those of our clients carefully following news stories about healthcare companies know that many of the biggest and most recognized players have surprised their stockholders with losses of astonishing size, announced seemingly without warning. But in today's world of big money, many of these companies became big without addressing the fundamentals of any good business.

My business experience tells me that any company which delivers a quality product that meets and exceeds the needs of its customers is guaranteed success, but only if its management team can competently execute a good business plan. Examples of this? **General Electric** gets lots of plaudits, and I think they are well-earned. One of my favorites is **Emerson Electric**. It has 36 consecutive years of record earnings and profits! Better known companies are **Federal Express**, which created an industry, and **Microsoft**, which seems to continually offer software with more features and lower prices than its competitors (although many of you curse the complexities of certain Microsoft programs).

Here's the point I want to make. You can read our editor's predictions of further hard times ahead for the healthcare industry on pages 4-6. He's probably right that healthcare's struggles to reinvent itself will tend to make it more difficult for clinical laboratories to earn a fair profit. His analysis is based on sound fundamentals, although he tends to downplay the equally serious impact of ongoing government interference in the healthcare market.

Here's the point I would like to make: although there will be gloom and doom for many healthcare providers during the next five years, there is also an opportunity for clinical laboratories to enjoy reasonable success. However... that success depends on a business capability not yet widespread in the laboratory industry. That business capability is management skills combined with the courage to initiate change.

In any economy, in any industry, at any time in the market cycle, you can find successful businesses. They are the ones with a value-added product, close attention to their customers' needs, and good management implementation. I believe such managers are emerging in our industry. That is why I believe that optimism about our industry's future is justified and appropriate.

THE DARK REPORT / August 17, 1998 / 2

United Health's Big L Derail Merger With Humana

United Healthcare Corp's \$900 million charge comes as unpleasant surprise to Wall Street

CEO SUMMARY: Considered the darling of the managed care industry by investors, United Healthcare's huge write-down makes it the latest healthcare behemoth to post an immense loss. Laboratory executives should see this as a sign that even big healthcare companies are struggling to develop fiscal stability. Medicare HMOs are believed to be one major source of United Healthcare's big loss. That is another warning flag for the clinical laboratory industry.

ALL STREET WAS STUNNED WHEN United Healthcare Corp. disclosed a \$900 million charge on second quarter earnings. Within days of the announcement, made on August 6, the merger between United Healthcare and Humana Inc. was cancelled by mutual agreement.

"Your jaw drops when you see the charge. It's enormous," commented Todd Richter, financial analyst at Morgan **Stanley.** "I don't think anyone expected it."

The charge caused a second quarter loss of \$565 million at United Healthcare and a decline in market capitalization of \$2.9 billion. Only two years earlier, a similar surprise announcement of an earnings shortfall caused the market capitalization of United to fall by \$2.3 billion in one day.

This most recent decline in United's stock price meant that the Humana deal dropped from a value of \$6.3 billion to only \$4.1 billion. United Healthcare withdrew its tender offer after discussions with Humana.

If the merger had gone through, it would have created the largest managed care entity in the United States. The merged entity would have insured 19.2 million people in all 50 states, and boasted revenues of \$27 billion. (See TDR, June 15, 1998.)

It was predicted by THE DARK REPORT that the United-Humana merger would affect the way clinical laboratory contracts were negotiated in a number of states. Given the size and clout of the merged company in states like Florida, Texas, and Ohio, new laboratory arrangements, at tighter reimbursement terms, were expected.

For laboratory executives, the developments at United Healthcare provide a valuable peek at the financial challenges

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 1731 Woodland Terrace Center, Lake Oswego, Oregon 97034, Voice 1.800.560.6363, Fax 503.699.0969. (ISSN 1097-2919.)

R. Lewis Dark, Founder & Publisher.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, Which includes THE DARK REPORT plus timely briefings and private teleconferences, is \$10.80 per week in the US, \$11.40 per week in Canada, \$12.45 per week elsewhere (billed semi-annually). NO PART of this Intelligence Document may be printed without written permission. Intelligence and information contained in this Report are carefully gathered from sources we believe to be reliable, but we cannot guarantee the accuracy of all information.

Robert L. Michel, Editor. © The Dark Group, Inc. 1998.

All Rights Reserved.

threatening the entire managed care industry. Because managed care plans contract and pay for laboratory services, any financial problems they experience directly affects reimbursement for clinical laboratory services.

Plainly put, if a managed care company finds itself in a cash flow squeeze, it would be unable to pay its providers and vendors, including clinical laboratories. **Oxford Healthcare** and **FPA** are two recent examples of exactly this problem. Both companies found themselves unable to pay contracted reimbursements to physicians and other providers on a timely basis.

Because managed care plans contract and pay for laboratory services, any financial problems they experience directly affects reimbursement for clinical labo-ratory services.

United Healthcare's business problems provide early warning to laboratory executives on a number of market issues which are common to most managed care companies. This is especially true of United Healthcare, because the company was considered to have one of the best information systems in the industry. In theory, they had better knowledge of cost trends and utilization patterns than other managed care companies.

THE DARK REPORT also believes one unique issue in United Healthcare's \$900 million charge should be carefully watched by lab industry executives. It is the problems experienced by United Healthcare in servicing both the Medicare HMOs and its **American Association of Retired People's** (AARP) health insurance program, which is a supplemental fee-for-service plan offered to AARP's 32 million members.

"They're clearly writing off a significant chunk of Medicare," observed Peter Costa, analyst at **ABN AMRO**. "They're reducing exposure in more than 35 counties and curtailing start-up efforts in four others. Medicare was a big startup area for United and clearly it is not working out as desired."

Key Laboratory Trend

Costa's comments focus attention on a key trend affecting clinical laboratories. The demographic growth of the Medicare population guarantees that any Medicare-related healthcare product will be significant in coming years.

The federal government wants private managed care plans to play a greater role in the Medicare program. But here is evidence that the existing combination of federal reimbursement and United Healthcare's management of the Medicare HMOs has been unable to generate sufficient profit margins to sustain these regional HMO operations.

United Healthcare is not the only major managed care company over-hauling its Medicare HMO programs. Anthem Blue Cross/Blue Shield pulled its Medicare HMOs out of 19 Ohio counties. Pacificare Health Systems ceased Medicare HMO operations in southern Oregon and intends to quit Utah and portions of Washington.

Abandon Medicare Business

These are just a few examples of managed care companies which decided to abandon the Medicare HMO business. THE DARK REPORT predicts that reimbursement for services provided under the Medicare program will fail to keep pace with inflation.

The result is that even Medicare feefor-service reimbursement will fail to cover provider costs. This will continue one source of the financial squeeze on clinical laboratories.

(For further information, contact Robert Michel, Editor, at 503-699-0616 or email to: labletter@aol.com.)

"Corporatized" Healthcare Encountering Big Losses

HMOs and PPMs find sustained profits to be elusive in world of managed care

CEO SUMMARY: When the clinical laboratory industry found itself losing hundreds of millions of dollars in recent years, few people imagined that billion-dollar HMO and PPM com-panies would soon experience similar losses. Current trends in the managed care marketplace indicate that prob-lems for these huge healthcare companies translate into con-tinued downward pricing pressure for laboratory testing.

Recent events suggest that huge financial losses suffered by the clinical laboratory industry during the 1995-1997 time period will not be unique within the healthcare world.

When **United Healthcare Corporation** disclosed a \$900 million charge and a \$527 million loss for second quarter last week, industry experts were caught dumbfounded. After all, this was the managed care company considered to be the darling of the industry.

But United Healthcare's financial woes are consistent with the experience of a large number of health insurance plans. Oxford, Foundation Health Systems, and Kaiser Permanente are just a few of the huge companies which reported losses during the last 12 months.

Their experience is not isolated. Throughout the United States, many regional health plans also posted losses during 1997 and the first half of 1998. This recent wave of widespread financial instability within the health insurance industry caught analysts off guard. Further, there is no clear consensus as to when finances may improve for health insurance companies.

Physician practice management (PPM) companies are another health-care segment posting surprising financial losses. Highfliers like **MedPartners, Inc.** have hit the financial stone wall even as the investor community was flocking to acquire stock in almost any PPM company.

Allegheny's Bankruptcy

Further, the recent bankruptcy of Allegheny Health Education and Research Foundation's Philadelphia operation may be an early sign that more than a few hospital systems will soon be forced to publicly declare that their financial position is precarious. Allegheny's eight Philadelphia hospitals are losing \$26 million per month, or \$292 million per year! Expect similar announcements of poor finances by other hospitals and health systems over the next 18 months.

None of this should be a surprise to clients of The Dark Report. We have been firm in our conviction that all segments of healthcare will undergo significant financial and organizational restructuring in the next few years.

Pressures to reduce healthcare costs by the buyers (employers and the government) directly conflict with the desires of users (patients), who want high quality healthcare and immediate access. The increased cost of new healthcare technology only compounds the cost control problem.

Radical Change

That is one reason we believe that economic, social, and political forces acting upon healthcare will continue to force radical change upon all aspects of the industry. Our experiences during the last eight years represent the early stages of a dramatic and radical overhaul to the entire healthcare system.

Commercial laboratories were probably the first segment of health-care to sustain several financial losses. Hospital laboratories are undergoing a similar period of widespread consolidation and reduction to capacity.

Clients and readers of THE DARK REPORT should understand that Oxford and United Healthcare (managed care companies), MedPartners and **FPA Medical Management** (PPMs), Allegheny and other hospital systems are simply the first victims in the coming wave of financial stress to their particular segment of healthcare.

Severe Revenue Cutbacks

Just as the commercial laboratory industry was hit with severe cutbacks to revenue and profits, so also will PPMs, managed care plans, and hospitals undergo a similar process.

This will not be good for clinical laboratories. These are the main users and buyers of laboratory testing. If they cannot make sufficient operating profits to sustain their own operations, they certainly cannot be generous with their reimbursement for laboratory testing.

The future is not promising for the laboratory industry. During the next five years, clinical laboratory finance will be affected as much by the finances of other healthcare providers as with the value-added services and impact of new diagnostic assays offered by clinical laboratories.

For this reason, it is important for laboratory executives to understand that these huge losses will not be isolated to a few companies. Look at the underlying economics.

Within the healthcare insurance industry, large companies are dealing with two fundamental problems. First, they do not have effective information systems. Large HMOs and insurers find themselves unable to collect timely and usable data on medical costs and utilization. They are not able to give providers accurate and timely lists of beneficiaries.

Underprice Their Premiums

The direct consequence of this failing comes at rate renewal time every fall. When HMOs establish premium rates, they underestimate their actual costs, causing them to underprice their premiums. They are then forced to adhere to those unprofitable premium rates for an entire year.

Second, during the last two years, middle America's unplesant experiences with how closed panel HMOs limited their choices caused them to buy healthcare insurance differently. They now pay an extra premium to get the option which allows them to go out-of-plan for service.

During 1997, a significant number of HMO enrollees exercised this choice option and used outside doctors. The higher costs incurred as a result of this trend caught HMOs by surprise and contributed to widespread industry losses by year-end.

In the physician practice management company segment of healthcare,

easy money days have ended for large corporate operators like FPA, MedPartners, and PhyCor. Their rapid growth and financial success was based more on acquisitions of additional practices than it was from improved management of acquired physician practices.

For five years or so, that made them the darlings of Wall Street. But now that these companies are big, multi-billion operations, they face an unsolvable management problem: how do they get each clinic or physician practice to increase revenue, increase productivity and decrease costs year after year?

Motives Of PPM Executives

THE DARK REPORT believes that there is no fundamental alignment in the motives of PPM executives and the physicians working for their company. As a result, it will be nearly impossible for MedPartners and other PPMs to generate "same store" growth rates of 10% to 15% per year at individual practice sites.

The hospital segment has a capacity problem. There are too many hospital beds in most metropolitan markets. Politics being what it is, closing hospitals is a rare occurence. But sooner or later, the people who pay the bills will refuse to subsidize empty hospital beds. Only then will the supply of hospital beds decrease enough to meet demand.

Market Directions

What lessons should be drawn from these developments, and the market directions they seem to point to? First, clinical laboratories should begin to do their own evaluation of the financial condition of managed care plans and PPMs. It serves no useful purpose to get the contract for laboratory testing, if sometime within the contract's term the contractor cannot pay laboratory testing bills, leaving the lab holding unpaid invoices.

Huge Losses Posted By Many Companies

- 1. United Healthcare Corp.

 Reports \$564 million loss for second quarter, due to a \$900 million charge.
- 2. Oxford Health Plans, Inc.
 Reports a \$508 million loss for
 second quarter, comes on top
 of similar losses posted during
 the last six months.
- 3. Allegheny Health Institute And Research Organization:
 Puts eight Philadelphia hospitals in Chapter 11 bankruptcy with ongoing losses of \$26 million per month.
- **4. FPA Medical Management:** Files Chapter 11 bankruptcy and posts a \$200 million loss.

Financial losses at certain PPMs and the bankruptcy of FPA should be a warning to pathologists about the downside of PPMs. The financial woes of many large PPMs come just as pathology-based PPMs are entering the marketplace and seeking to purchase pathology practices.

For example, some physicians in California sold their practice to FPA in January and received stock worth \$18 per share as payment. After FPA's big losses and the subsequent bankruptcy in July, the FPA stock held by these physicians was worth less than \$0.20 per share!

Laboratory executives and pathologists should keep track of how well these companies do over the next 24 months. Their success or failure provides a good market indicator of where the healthcare industry is heading. Should additional companies also post extraordinary losses, it will be tough for clinical laboratories to generate revenue growth and operating profits.

AACC Convention Exhibits Point To New Lab Trends

Modular automated lab instruments favored over total laboratory automation solutions

CEO SUMMARY: This year the interesting trend at the AACC's exhibit hall was modular laboratory automation. That's a big change from the total laboratory automation solutions touted in past years. But watch out! The eco-nomics of this equipment have yet to be validated. It was also clear that another coming trend is the globalization of clinical laboratory services.

URING THE WEEK OF AUGUST 3-7, the American Association of Clinical Chemistry (AACC) held its annual convention in Chicago. The scale of this program is immense. More than 18,000 people attended, of which 20% were from other countries.

Despite the reduction in the number of laboratory sites in the United States and consolidation in the diagnostics industry, a record number of exhibitors showed up in Chicago. There were 530 exhibitors and 1,400 booths. At least 130 exhibitors were at AACC for the first time.

"Off-The-Record" Briefings

THE DARK REPORT was invited to attend a number of special functions during convention week. Most were "off-the-record" background briefings, but all contained a wealth of useful intelligence about future directions for the clinical laboratory marketplace.

There are two key observations for our clients and readers. First, the AACC convention is physical evidence that a globalization of clinical laboratory services and organizations is in its infant stage. Diagnostics vendors from Asia and Europe were highly visible, as were attendees from a multitude of countries around the world.

Further evidence of this globalization trend was confirmation during conference week that several leading laboratory organizations in the United States are actively marketing their laboratory testing services in foreign countries. Of equal interest, the strategy of at least one major laboratory organization is to purchase and operate clinical laboratories in other countries. This lab has already completed several overseas acquisitions.

The globalization of lab services will have positive effects for the laboratory industry in the United States, as it opens new revenue sources for both clinical laboratories and diagnostics companies based here in the U.S.

Second, if actions speak louder than words, then total laboratory automation (TLA) is a non-issue at this stage in its development curve.

The reason? Vendors were willing to talk about TLA, but their time and money has been invested in developing automated instrument modules and work cells. These were the products which garnered the most hoopla and attention.

It seemed that every diagnostics vendor capable of designing such a system had done so, exhibiting clusters of instruments formed together into self-contained automated work modules. But are these instruments ready for market? And were attendees buying?

No To Both Questions

It seemed that the answer was no to both questions. Of the advanced automated instrument modules displayed, few are actually ready for sale and immediate delivery.

One perceptive attendee commented, "I am hearing release dates as far out as third quarter 1999. Even if I put cash on the barrelhead today, my laboratory would have to wait for months before most of the advanced modular automation work cells I'm interested in could be installed and working in my laboratory."

Her comment was consistent with the information gained by THE DARK REPORT in visiting exhibits and speaking with other attendees. It led us to make a comparison. The software industry has a term for companies which announce new software products, with a release date far in the future (and which may never be achieved). That term is "vaporware."

Described As "Autoware"

So what would be the term for an automated modular workstation, which currently exists only as a manufacturing prototype and won't be available until some specified point in the future? Some wags in our group coined the term "autoware."

If the metaphor is valid, then diagnostics vendors displayed their particular brand of "autoware"—prototype automated laboratory instrument modules which are not yet ready for operation in a clinical laboratory. That should be a caveat to those laboratory administrators pondering whether to purchase

this upcoming generation of unproven automated instrument modules.

As with total laboratory automation, this technology needs to undergo further development and refinement before it demonstrates a clear-cut effectiveness over current technology.

Our recommendation is that laboratory executives who want to be early adopters of this generation of laboratory automation modules should get a performance guarantee from their vendor.

"Even if I put cash on the barrelhead today, my laboratory would have to wait for months before most of the advanced modular automation stations I'm inter-ested in could be installed and working in my laboratory."

After all, if the vendor is convinced this generation of its product can deliver economic and productivity improvements, then it should stand behind that belief. Such a contract would be winwin for both parties.

During the next 12 months, THE DARK REPORT expects that laboratory executives will find a steady stream of instrument vendors offering this first generation of laboratory automation modules. The obvious evidence supporting this prediction was the money and effort invested by diagnostic companies to launch these products at the AACC convention. Expect similar exhibits, although on a smaller scale, at CLMA's convention this week in Philadelphia.

Just as 1996-97 was the year for marketing automated cytology systems to the laboratory industry, so also will 1998-99 be the year for marketing automated laboratory modules. **TDR** (For further information, contact Robert Michel at 503-699-0616 or email to: labletter@aol.com.

Advice From The Other Side Of The Table

Blunt Talk From HMO Blue's Ancillary Contracts Manager

PROVIDER STATUS IS NOW THE HOLY GRAIL for clinical laboratories and pathology practices. With provider status comes access to patients and the opportunity to build market share.

In fact, provider status is now so important that the clinical laboratory world is fracturing along the fault line of provider status. Those laboratories which gain provider status with major managed care organizations (MCO) in their city enjoy a better financial performance than labs which are excluded from the MCOs' provider panels.

Despite the importance of provider status, the MCO's selection process remains a mystery for many laboratory executives. That is why THE DARK REPORT invited the provider network director of a major HMO to address the *Executive War College* held last May 12-14 in New Orleans.

"When any laboratory or pathology practice seeks to become approved on our provider panel, it must first understand the needs of people with my responsibility," stated John Monaghan, Director of Network Development for **HMO Blue** of New Jersey. "What are the demands of our job? What goals must we meet for our MCOs to succeed? What is the exact type of deal we want to make with clinical laboratories who join our provider panel? The first advice

CEO SUMMARY: By now, most clinical laboratory executives and pathologists have discovered a new fact of life: provider status with managed care orga-nizations is a critical success factor. Without provider status, the laboratory is denied access to patients and the reimbursement associated with those patients. Here is candid information about how and why a managed care organization selects some labo-ratories as providers and excludes others. It is reveal-ing reading, and should be used by perceptive man-agers and pathologists to refocus their laboratory organization on the clinical services which matter most in the managed healthcare world of tomorrow.

I give to providers is 'Know your customer.' And I am your customer."

Monaghan's HMO covers 600,000 lives and is a for-profit subsidiary of **Blue Cross & Blue Shield of New Jersey**. It is a regional mixed model network incorporating an independent physician association (IPA), Group, and Staff Models. HMO Blue provides services in New Jersey and Pennsylvania. It has applications pending for authorization to launch operations in New York and Delaware.

Monaghan develops and manages the provider networks used to deliver clinical services. Within HMO Blue, he is the individual who supervises the RFP process and deals with problems between providers, physicians and patients.

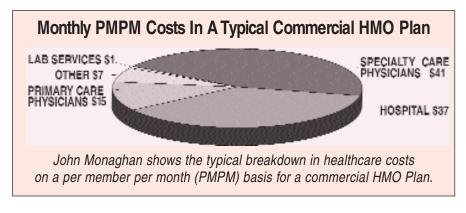
"I frequently describe myself as the most obnoxious SOB you'll probably meet in the managed care business," said Monaghan. "I say that for two reasons. First, I take my job seriously. I look upon our vendors as the people who will be providing medical care to my family. For

"Second, like other MCOs, change is constant within our company" he continued. "For that reason, I must be tough in making decisions and implementing those decisions with our vendors and physicians. That leaves me little time to dwell on clinical laboratories to the exclusion of other providers.

"On the other hand, I can probably be the most valuable reference you'll have in the managed care world," Monaghan noted. "My office deals with all ancillary providers. So I deal with hospices, skilled nursing facilities (SNF), dialysis facilities, and the like. When you go to these facilities, I can be a fairly good advocate for your organization if our working experience validates your organization's capabilities."

Monaghan's background gives him unusual credibility within the managed care world. He has actuarial training and spent five years underwriting national accounts. Following that came five more years of progressive experience in managed care contracting.

"During my days as an underwriter," said Monaghan, "I saw first-hand the reasons why large employers migrated toward managed care during the late 1980s and early 1990s. I've had to go out and explain to companies like **IBM** and **AT&T** why



their health premium rate renewal was increased by 62% on both the medical and hospital segments.

"This gives me a leg up on industry colleagues in other HMOs that you may deal with," he added. "As a former underwriter, I understand the numbers that go into the rates and how the rates are developed into final premiums. I understand why employers are selecting managed care programs for their employees."

Where The Money Goes

"Many of the insights I want to share with you derive from understanding where the money goes in the healthcare community," stated Monaghan. "As the pie chart (above) demonstrates, typical PMPM (per member per month) costs total about \$100 per month. Of that, laboratory costs average around \$1 PMPM. Even the highest I've seen for laboratory is only \$4 PMPM.

"Look at lab expense in relationship to everything else," he added. "Laboratory is not the big cost item within the healthcare system. That is the major point I want to drive home. I realize that laboratory is 100% of your business. But it is only a small portion of mine. My time and focus is on other areas, not laboratory.

"Although my major concentration is spent on more significant priorities than clinical laboratory, continued Monaghan, "I fully appreciate the potential of laboratory testing to favorably impact both the quality of healthcare and the cost of care. HMO Blue does want clinical laboratory services to be an asset for our provider networks. We also seek to address test utilization.

"That is precisely why I want every laboratory provider to ask this question of themselves during the RFP process: 'Do you know your laboratory organization?' As the provider selection process takes place, it is absolutely essential that you understand what your laboratory is and how it matches the particular needs and criteria of HMO Blue."

Know Your Laboratory

"I've provided two lists of characteristics that you should compare," said Monaghan. "One list is about your own laboratory organization. The other list is about the specific needs of HMO Blue from our designated laboratory provider(s). Before entering into the RFP process with us, you would be well-advised to understand how your particular strengths match up with our needs for a laboratory provider."

Monaghan's advice is simple: Laboratory executives need to do a comprehensive strategic analysis of their laboratory's capabilities. They must identify how their lab can do a better job serving HMO Blue than competing labs in the target region. A well-structured RFP response by the lab allows the MCO to make a more informed decision in favor of the best-qualified laboratory.

"Before going further, I want to lay to rest the argument about quality that I constantly hear from laboratories," Monaghan said. "Does your laboratory really understand the concept of *quality customer focus*? At HMO Blue, this is an important trait we look for in potential providers.

"The quality benchmarks I am interested in go beyond test result QA/QC," he continued. "The lab industry has a variety of accrediting agencies to handle that. CLIA, CAP, Joint Commission, and others already regulate laboratories. It's not a major point with me that you've processed 99.99% of your PSAs correctly or on time. I assume that your compliance with this measure of quality is 100%. What I want to know is how you serve your customers better than your competitors."

Lab Has Three Customers

"Any laboratory on our provider panel has at least three customers: physicians, consumers and the MCO itself. I want to know what you're doing to improve their perception of your service. I want to know what your plans are for *improving* existing satisfaction levels of your customers. It's not good enough to just stand still. Your laboratory should constantly be raising the bar by giving customers higher levels of service.

"I have a good example to illustrate this point. Magee Rehabilitation Hospital in Philadelphia is one of the foremost rehab facilities in the United States," observed Monaghan. "When I asked them this question, they had an intriguing answer. After surveying their customers, they discovered everyone coming from the outside hated their cafeteria. So they made a substantial investment to improve the cafeteria. Magee was willing to put money and action behind the service deficiencies identified by their customers.

"Laboratories can do the same thing. Are you able to show me that your ASCUS rate on Pap smears is

Do You Know Your Lab Organization?

- 1. What are you doing about quality and customer focus?

 Meetings, posters, lunches, surveys?
- 2. Which products and services are most important to the lab's business? Draw stations, stat tests, Pap smears, laboratory test reports.
- 3. Who is the most important customer for these products?

Physicians, MCOs, consumers.

- 4. What are the most important characteristics of your product?

 How does your lab measure up with the competition?

 How do you know?
- 5. What are your plans for improving satisfaction? Member, physician, MCO.
- 6. Can you demonstrate tangible improvements resulting from your quality customer focus program?

lower than competing labs?" he asked. "If so, you allow me to prevent women from having unnecessary procedures and losing time from work. This is a *quality customer focus* that HMO Blue seeks from its preferred providers.

"But I am not going to sift through your data looking for this advantage," advised Monaghan. "You will need to take the initiative to brag about that. And you'd better have the data to back it up. If you do, I'm interested."

Another major area of interest to HMO Blue is access to service. "I manage a statewide network which is going into four separate regions," noted Monaghan. "So access is important to me. But access involves more than just physical locations. My customers, the patients, don't see their lab reports. They're unaware that the lab beat the five day turnaround time on Pap

smears by two days. What they see is your draw station. If you have people in your draw stations making low wage who don't care about what they are doing, you're in trouble with your RFP.

"Your draw stations need to be clean, accessible, and organized," he continued. "What is the first impression that a patient gets when he walks in? Is the draw done quickly, or must he wait?

"It is similar with physician service issues," added Monaghan. "Do you provide excellent turnaround time? I will never tell you what turnaround times should be, because you know your business better than I do. But I do care when a physician calls us to complain about missed pickups and late reports. Educate me about why your lab is better than competitors. Document why physicians believe your service is excellent. This helps me make a decision in your favor."

Does Your Lab Know HMO Blue's Needs?

1. Access to Service:

Draw stations-number and location. How many physicians do you service?

2. Service the Physician:

Provide excellent turnaround time. Is the report easy to understand? Can the physician speak with the pathologist easily?

Be proactive.

3. Service the Consumer:

Are draw stations clean and organized? What's the waiting time? Are phlebotomists consumer cognizant?

4. Service the MCO:

Be a lab consultant.
Identify trends.
Identify areas for improvement.
Communicate about problems
and service issues.
Do not overextend.
Resolve complaints in a timely way.

Pathologist Involvement

Another interesting area discussed by Monaghan involved pathologists. "Can the physician easily contact the pathologist? A big issue and problem we deal with is when tests are outsourced or referred elsewhere. Your pathologists need to be ready to talk to our network physicians.

"But my experience is that most pathologists don't do this very well. Radiologists learned this service skill ten years ago. They've made themselves more effective in this role and they are making more money because they have figured this out."

Monaghan's point should not be overlooked by pathologists. He is referencing both an attitude of service and an acquired skill of interacting with fellow physicians. Radiologists now operate in a way that enhances the clinical effectiveness of their professional colleagues. Monaghan implies that pathologists might get paid more for their services if they learned the same lessons about customer service as radiologists.

Where Labs Have Value

"One area where laboratories have incredible value for me which they seldom use is in reporting," declared Monaghan. "I need data in a timely fashion, not three months after the end of the quarter. But what I really want is laboratory data that makes a difference. Can you identify trends?

"You are the first people to know what the test results are," he said. "My case managers fall out of their chairs if they get a call from the laboratory saying 'look what we found.' Were you to demonstrate that trait of being a patient advocate, I would always want to keep you on our provider panel.

"HEDIS (Health Employer Data Information Set) is another opportunity. You want more money for your lab? Write into your contract that if HEDIS results improve because of what you do, you get more money," explained Monaghan. "But be ready for the downside. If HEDIS results decline or stay the same, I may ask for you to put some money back on the table. It's the same with NCQA (National Committee on Quality Assurance). Each year that I must undergo accreditation, it costs me money. If you help with information that improves the accrediting process, I can do something for your lab.

"Innovation counts as well. Can your laboratory link test results with pharmacy prescriptions? Some labs are talking about doing that. If you could achieve that, your lab would be more valuable to me and reimbursement could increase appropriately. Disease management and prevention is another obvious area of added value."

Insignificant Leakage

"Leakage is an issue," he continued. "There is a good reason for HMO Blue's long-standing contract with **Laboratory Corporation of America**. In just a couple of years I've gone from a very small network to a large network. My leakage is almost insignificant. If I am going to deal with another laboratory vendor in my service area, that lab must be prepared to deal with leakage."

Monaghan discussed a variety of other issues and opportunities with the audience at the *Executive War College*. But his theme was consistent. "To become a provider for any MCO, a laboratory must understand the needs and goals of the MCO," he said. "The only winning strategy for a laboratory seeking to join the provider panel is to provide hard data on its service performance and capabilities, and develop value-added services which align the laboratory and the MCO in a win-win fashion.

"My goal with these comments today is to help you understand, from

our side of the table, what makes a laboratory valuable to an MCO," he concluded. "Don't think that a simple written response to an RFP is going to open the MCO's door. Successful laboratories must invest time and effort into understanding the MCO's needs and demonstrating to the MCO why the laboratory is a good solution to those needs."

"Don't think that a simple writ-ten response to an RFP is going to open the MCO's door. Successful laboratories must invest time and effort into under-standing the MCO's needs..."

Monaghan's comments reinforce a consistent theme known to clients and readers of THE DARK REPORT: successful clinical laboratories understand the importance of value-added services. As Monaghan repeatedly stressed, HMO Blue is interested in a laboratory which can help it provide demonstrably better healthcare to its enrollees, physicians and employers.

Of particular significance is Monaghan's interest in clinical laboratory providers which understand the concept of *quality customer focus* and its importance. HMO Blue, like other managed care plans, wants to add laboratory providers which constantly upgrade the value of their services.

For hospital laboratory administrators and directors, this should be a clarion call to institute proactive change in their laboratory. Only those laboratories upgrading their customer service capabilities will be the ones to survive in coming years.

(For further information, contact John Monaghan at 973-466-8396.)

Lab Industry Briefs

Automated Cytology Update

As predicted by The Dark Report, the field of automated cytology has become a boiling pot, filled with controversy and change. Profits are meager. As we expected, the major issue revolves around the cost of this enhanced technology versus the measurable clinical benefits it delivers over traditional Pap smear procedures. Here's a quick round-up of developments.

ACCUMED IS RELISTED AND NOW PLACING UNITS

As of July 24, 1998, AccuMed International, Inc. shares again trade on the Nasdaq market. In March the company was delisted because it failed to meet Nasdaq's qualifications.

Meanwhile, new president Paul F. Lavallee has been busy. AccuMed's AcCell™ Systems are being installed in a Chicago teaching hospital and an integrated healthcare provider in the Seattle area. AcCell is an automated cytology workstation which combines the microscope with computer-enhanced features to improve productivity and accuracy of the cytologist.

AUTOCYTE SIGNS DISTRIBUTOR AGREEMENTS, LABCORP ORDER

AutoCyte, Inc. continues to await FDA action on its premarket approval (PMA) applications for the PREP™ and SCREEN™ Systems. It is building its distribution system during the interim.

The company announced distribution agreements with **Medical & Biological Laboratories Co.**, LTD (MBL) of Nagoya, Japan. In one agreement, MBL acquired exclusive worldwide rights to distribute AutoCyte's ImageTiter®, a proprietary system which enables the quantitative assessment of anti-nuclear antibodies in a patient's blood specimen. The other agreement gives MBL exclusive

distribution rights to the AutoCyte Pathology workstation for Japan, Korea, and Taiwan. MBL made initial payments of \$1.3 million to AutoCyte as part of these agreements.

Laboratory Corporation of America placed a \$600,000 order with AutoCyte for ImageTiter Systems and system upgrades. AutoCyte is using the ImageTiter Systems as a revenue source while awaiting FDA approval for its automated cytology products.

CYTYC CORP BESIEGED BY MEDIA ATTENTION

During 1997, **Neuromedical Systems**, **Inc.** and its PapNet[™] product was the whipping boy among automated cytology companies. This year, **Cytyc Corp.** seems to have assumed that role.

Since the end of 1997, Cytyc's revenues and operating profits have disappointed financial analysts and stockholders. These revenue numbers indicate that market acceptance of Cytyc's ThinPrep® monolayer Pap smear technology has been underwhelming.

Despite this fact, Cytyc's public releases continue to tout the fact that "over 6,000 gynecologists and 400 cytology laboratories across the country have begun to use the ThinPrep Test as a replacement for the conventional Pap smear."

For those with detailed knowledge of cytology and clinical laboratory practices, Cytyc's comments seem to borrow from

the techniques of the White House spinmeisters. Cytyc's revenues fail to meet targets because clinical use of ThinPrep Pap smears has never grown as rapidly as the company projected.

Further, *The Wall Street Journal* ran a cover story about Cytyc's ThinPrep test and the controversy surrounding it last Friday, August 13. Clients of THE DARK REPORT are advised that it makes thoughtful reading.

Headlined "A New Pap Test Costs More, but Is It Worth It? Some Think Not," the story talked about how health insurers believe the additional cost of the ThinPrep Pap smear is not justified by the incremental improvement in early detection of cervical cancer.

According to *The Wall Street Journal*, on the same day that the **American College of Obstetricians and Gynecologists** (ACOG) decided not to endorse ThinPrep as a standard of care, Cytyc released news that **CIGNA Healthcare** would offer coverage for ThinPrep testing.

Cytyc responded to the ACOG's negative decision on ThinPrep with a press release worthy of the White House spinmeisters. Cytyc stated that "the company believes that the ACOG Opinion on new Pap test screening techniques released this week is a fair and balanced technology assessment that confirms the positive results of extensive clinical studies of Cytyc's ThinPrep Pap Test."

As discussed in previous issues of THE DARK REPORT, the battleground for automated cytology technology is cost versus clinical efficacy. Cytyc's \$40,000 instrument and \$9.75 charge per Pap smear slide makes it an expensive option when compared to traditional Pap smear procedures, especially when measured against specific improvements documented in clinical trials of the ThinPrep System.

The Wall Street Journal story also touched upon Cytyc's struggles with the **Food and Drug Administration** (FDA). In July, 1997, the FDA received seven

petitions from individuals with links to competing cytology companies. These petitions seek to have the FDA review its decision to approve ThinPrep. The FDA has yet to act upon these petitions.

There are more details to this story involving Cytyc. To gain a better appreciation of the debate, clients should access ACOG's report, *The Wall Street Journal* article, as well as press releases and company material on these issues.

Regardless of what happens to Cytyc, the issues now in public debate between physicians, insurers, and automated cytology companies provide laboratory executives with a perfect example of how new laboratory technology must demonstrate clear and unequivocal cost and clinical efficacy before it will be adopted on a widespread basis.

MORPHOMETRIX TO USE "INTUITION" IN CYTOLOGY

Most laboratorians are gradually becoming aware of a cytology start-up company called **Morphometrix Technologies**, based in Toronto, Canada.

Morphometrix is working to develop its version of an automated cytology screener. To aid its development of the necessary software algorithms, Morphometrix is working with a company called **Klein Associates**.

Here's where it gets interesting. Klein Associates is developing methods that allow them to identify and "map" the techniques used intuitively by physicians and other professionals. Klein's work demonstrates that "subjective" rules can be identified scientifically and converted to objective, rule-based, decisionmaking formulas.

Morphometrix is working with Klein Associates to identify what techniques cytologists use to identify irregular cells. The goal is to convert "I know it when I see it" into a definable, step-by-step process. "This is a huge area, and I think we're going to get some startling results," says Morphometrix executive Dan Maclean.

Morphometrix wants to use the results of Klein's work to develop sophisticated software algorithms that improve the speed and accuracy of its automated cytology system.

CANADA APPROVES NEUROMEDICAL'S PAPNET FOR PRIMARY SCREENING

It was a long-awaited event for **Neuromedical Systems, Inc.** of Suffern, New York. The company has approval to use its PapNet® System as a primary screener in Canada.

The Therapeutic Products Program Medical Devices Bureau of Canada notified Neuromedical that "the PapNet Testing System meets the Canadian Regulatory Requirements For Notification as per Part II of the Medical Devices Regulations."

In the United States, the FDA granted approval for PapNet to be used as a supplemental Pap smear test. Several European countries have approved PapNet for primary screening. Canada's approval increases PapNet's credibility with prospective buyers.

Neuromedical now has clearance to market its PapNet System as a primary Pap smear screener in Canada. The company intends to market the product in the form of a self-contained system which is operated on the premises of each lab customer.

This is a change from its centralized processing strategy of 1996. Under that arrangement, participating labs sent their Pap smears to Neuromedical's central laboratory in Suffern. Here the Pap smear was scanned. The file and the slide were then returned to the referring lab for diagnosis.

Because cost of healthcare is a big issue in Canada right now, Neuromedical faces the challenge of demonstrating both cost and clinical efficacy of its PapNet technology before it can expect widespread sales success.

NEOPATH UNDERGOING MANAGEMENT CHANGES

Recent developments at **NeoPath, Inc.** may indicate a shift of strategy. Current President and CEO Alan Nelson, Ph.D. is moving to Chairman and the company announced that it is searching for a new president.

Knowledgeable observers believe that NeoPath in now positioned for growth. Earlier this year the FDA approved its PMA supplement for the AutoPap System to be used as a primary screener. With each month, the company accumulates an increased amount of clinical data from Pap smears screened by its customers.

If the experience of current users demonstrates favorable economics while delivering acceptable improvement in clinical outcomes, NeoPath should be able to make a strong case when selling its AutoPap Primary Screening System.

Assuming that to be true, then switching Alan Nelson to Chairman permits the company to bring in a new president. This individual would have a demonstrated track record in creating accelerated growth. Just as importantly, this new executive should have strong skills and sales and marketing.

Dr. Nelson is a savvy executive who has given NeoPath probably the smoothest development curve of any automated cytology company now operating. But a new set of executive skills is needed because NeoPath's venture capitalists and shareholders are ready to see a return on their investment.

It is THE DARK REPORT'S prediction that, when NeoPath's executive search ends, its new president will not have a clinical laboratory or diagnostics background. Rather, this individual will have proven experience at building the sales and profits of technology companies. If NeoPath succeeds in this quest, it will become a tougher competitor in the marketplace.

INTELLIGENCE ATENT LATE & Loo late to print, too early to report too early to report



THE DARK REPORT wants to thank those companies at the American Association of Clinical Chemistry convention in Chicago who invited us to special business briefings and other functions. It was an opportunity to meet both executives and the innovative customers of these companies who are advancing the art (and science) of laboratory management. Such meetings provide us with invaluable background knowledge to develop the useful business intelligence we provide our clients.

MORE ON...INVITATIONS:

Probably the most spectacular affair attended by The Dark Report was the **Beckman-Coulter Corp.** dinner in Chicago. Imagine an intimate dinner for 1,200 of your best customers, entertained by a 40-piece orchestra and three vocalists! It was the first time since the two companies merged that they have had their common customers in one place at one time.

LAST ADD TO...AACC:

Clients and readers of THE DARK REPORT should also know that entire staff of the AACC, including current president Michael Parker, Ph.D., went out of their way to insure that we learned of things which would have the greatest business value for our clients and readers. Similar efforts were made Sysmex Corp. of America Nichols Institute Diagnostics. Thank you!

One California lab's turnaround story continues. Second quarter revenues

Unilab Corporation increased from \$54.0 to \$54.5 million. Most importantly, net income jumped from last year's \$50,000 to \$3.4 million. Of further interest, specimen volume declined 4%, but prices increased about 5%. Because of California's highly-competitive lab environment, it is closely watched as a source of managed care trends which may later migrate to other cities.

CRITCHFIELD LEAVES QUEST FOR MYRIAD

Quest Diagnostics Inc. has lost their Chief Medical and Science Officer. Gregory Critchfield, M.D. announced his departure to become president of Myriad Genetic Laboratories, Inc., a subsidiary of Myriad Genetics, Inc. of Salt Lake City. Myriad expects that Dr. Critchfield's experience will help it place its molecular genetic diagnostic products into both commercial laboratories and the clinical community.



Laboratory Corporation of

America completed its acquisition of the laboratorv assets of Universal Standard Healthcare, Inc., located Southfield. in Michigan. (See TDR, July 27, 1998.) As part of the transaction, LabCorp purchased stock in Universal Standard. Larry Leonard, Ph.D. and director of LabCorp's western operations, will join Universal Standard's Board of Directors.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 7, 1998



UPCOMING...

- Going International: Why American Labs Now Chase Overseas Business.
- Cat Fight In North Carolina: MedPartners Withdraws From Blue Cross/Blue Shield.
- Pathology Practice Doubles In Size And Profits, In Just 30 Months.
- Interview With Clinical Laboratory
 Market Maker: Some Surprising Predictions.