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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Laboratory Information Systems "On the Cheap"

YOUR EDITOR AND I HAVE BEEN ATTEMPTING to make sense of the "Internet Revolution" in recent months. The ability of the Internet to make vast amounts of information available to anyone on demand, no matter where they are in the world, will definitely transform the clinical laboratory industry. After all, the fundamental product of any lab is the test data and information it produces.

But there is another aspect of the Internet which we are just beginning to comprehend. That aspect relates to the cost of LIS and other software used in the laboratory. Most of you are learning to distinguish between the fat client and the thin client–application service provider (ASP) business model for software. The fat model is what we know today. You buy the software from the vendor. You buy the computer hardware needed to run the software. Then you maintain software and hardware on your site. The thin client is just the opposite. The ASP provider creates the software. It is placed on a host, somewhere remote from the lab or hospital. The ASP vendor maintains the software and the hardware. The customer pays some ongoing fee to access and use the ASP software. All that is needed to access the remote host is a Web browser and a password for authorized users.

Most lab executives and pathologists know how expensive it is to acquire and maintain fat client software, such as the LIS and pathology software that runs most labs today. But few of us realize that, not only will thin client–ASP software services be simpler and easier to use, but the cost of thin client lab applications may fall to pennies. In one sense, this is what the Internet is doing to long distance telephone charges. During the past ten years, residential per-minute long distance fees have dropped from 25¢ per minute to 5¢ per minute and some experts think it will fall to nearly zero!

THE DARK REPORT see that the same process already occurring in Web-based lab test ordering and results reporting. In the second half of last year, **Healtheon/WebMD** was signing contracts with major labs for prices estimated to be about 50¢ to 75¢ per patient (for lab order and result). Earlier this year we reported how one lab, using **Abaton.com's** product, estimated its costs would be under 40¢ per patient. Now, as new companies enter the market, prices are falling further. Because a remote host–ASP vendor incurs virtually no added costs to hook up additional users, I think free market competition will drive the cost of ASP lab information software down to a fraction of what it costs today to maintain fat client systems! TDR

HMO Decline Predicted As PPOs Gain Enrollment

Hefty premium increases are expected to slow the annual rate of increase in HMO membership

CEO SUMMARY: Managed care analyst Michael Casey believes HMO enrollment will peak, possibly in 2000. PPOs (preferred provider organizations) are gaining members at an increasing rate. Within California, the provider revolt over deficient reimbursement levels is escalating. Orange County's largest medical group, with 500 doctors, announced it would not accept new HMO contracts and might possibly cancel existing contracts.

EXPECT LOTS OF CHANGE to the managed care health insurance industry during the next 24 months. Several economic and social trends are reshaping the HMO model for healthcare services.

"First, although the number of enrollees in HMOs nationwide increased during 1998 and 1997, the year-to-year rate of increase in HMO enrollment is declining" stated Michael Casey, Managed Care Analyst at **Medical Data International, Inc.** of Irvine, California.

"Second, the most recent data shows that enrollment in PPOs (preferred provider organizations) is increasing faster than enrollment in HMOs," added Casey. "I believe this trend will continue, for a number of reasons.

"Third, hefty increases in HMO premiums for 1999, 2000, 2001 are causing both employers and consumers to look differently at their health insurance options," said Casey.

"Fourth, many physicians, hospitals, and other healthcare providers are unable to remain financially solvent at the reimbursement offered by many HMOs," observed Casey. "Their difficulties must be addressed by HMOs, otherwise HMOs will not be able to operate in certain markets."

For clinical laboratory executives and pathologists, this means more changes in the way managed care companies contract and reimburse for laboratory testing and anatomic pathology services. But some of these changes may lead to better HMO con-

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tract terms and reimbursement for laboratory services.

Michael Casey is the author of the 2000 edition of the annual *Health Maintenance Organization (HMO) Penetration Rate Survey*, produced in each of the last seven years by Medical Data International (MDI) Casey's study reported that the nationwide penetration rate for HMO enrollment climbed to 30.5% for 1998, compared to 27.5% in 1997. Statistical data for 1999 will not be available until later this year.

"1998 was clearly a year for continued gains in HMO enrollment nationally, as 33 of the nation's 50 states showed increased HMO enrollment," said Casey. "In California, 55% of the population is now in an HMO, compared to 47% in 1997. By comparison, HMO enrollment is 38% in New York State and 33% in Florida.

HMOs Grow In Urban Areas

"This steady movement into HMOs means that, as of the end of 1998, 80% of the nation's population centers now have at least one-third of their residents enrolled in an HMO. As of 1997, only half of urban regions had enrollments of one-third or more."

Standard Metropolitan Statistical Areas (SMSAs) with the highest proportion of HMO enrollment are: Sacramento–82%, San Francisco–72%, Rochester, New York–68%, and Buffalo–64%. On the low side, New Orleans and Wichita have HMO enrollments of just 24%. Alaska has no HMO enrollees.

Casey feels this may be the high-water mark for the HMO movement in the United States. "If you follow the changes that HMOs are announcing around the country, you can see a common theme to these changes. Consumers want their own doctor, and they want the ability to chose their specialists. HMOs are responding to this consumer pressure by loosening gatekeeper restrictions and easing out-of-plan requirements.

HMO Models To Evolve

"As this trend continues, I predict that all HMO models will be reduced to what is, in effect, a modified PPO (preferred provider organization)," added Casey. "Consumer interest in PPOs is picking up. Data shows that, in most areas, PPO enrollment has begun to increase faster than HMO enrollment."

For laboratory executives and pathologists, Casey has an interesting recommendation. "The Internet is fundamentally changing the way patients, physicians, and providers interact with each other. Traditionally, laboratories and anatomic pathologists have had minimal direct communication with the patient. But increased involvement by consumers in their own healthcare will require labs to change this situation," explained Casey.

"I would encourage medical laboratories and pathologists to develop direct-to-patient services," he continued. "If this is done in cooperation with the referring physician, it will strengthen the bond between patient, physician, laboratory, and pathologist."

Rapid Evolution

Casey believes ongoing evolution away from managed care as we knew it in the 1990s will continue at a rapid pace. "Within five years, we probably won't be using the term 'managed care'," mused Casey. "Consumer expectations for a higher level of healthcare, combined with the demands of patients and their families for more responsive health services, will shift responsibility away from the managed care company and back to the physician and his patient."

Casey sees continued, even escalating battles between HMOs and

Large Doctor Groups Rebelling Against HMO Contract Terms

CALIFORNIA CONTINUES TO BE THE NATION'S bellwether for the ongoing evolution of managed healthcare. In Southern California, some physician groups are beginning to rebel against poor contracts

Orange County's largest medical group recently announced that it would no longer accept new HMO patients from the 17 managed care companies it currently serves. It is also considering cancelling these same contracts and withdrawing as a provider to these HMOs.

St. Joseph Health System's (SJHS) 500 physicians represent the largest medical group in Orange County. Its physicians serve 422,000 patients. SJHS says it loses $45 million per year on its HMO physician contracts and that capitated reimbursement is inadequate to provide proper healthcare. SJHS also notified **PacifiCare Health Systems** that it was terminating five of its 14 contracts between September and December 2000. This affects 40,000 of the 115,000 PacifiCare patients served by SJHS.

Over in Newport Beach, **Greater Newport Physicians** also sent notice to PacifiCare that it would not renew its contract for 2001. Greater Newport Physicians currently serves 40,000 PacifiCare patients.

Michael Casey, Managed Care Analyst at Medical Data International, says that low capitated reimbursement is behind these provider cancellations. "In 1993, capitated rates in California were typically $45 per patient per month. By 1999, these rates had dropped to $29, a level which is one-third below the national average, despite California's high cost of living," stated Casey.

The actions of St. Joseph Health System and Greater Newport Physicians are early signs warning that providers in California may start to withdraw from financially-unsustainable managed care contracts. As this occurs, California's healthcare system will go through another cycle of restructuring and change.

Clients and regular readers of THE DARK REPORT know that low levels of provider reimbursement in California have caused widespread bankruptcy and financial failure for physician group practices throughout the state. *(See TDR, October 11, 1999.)* This comes on the heels of widespread bankruptcies among California clinical laboratories during 1996-1998. These events demonstrate that California's system of managed care is failing to meet the financial and operational needs of its healthcare providers.

providers. "The main issue is money," he said. "On one hand, in many regions HMOs have squeezed provider reimbursement down to unsustainable levels. Providers legitimately want to see reimbursement increased.

"But on the other hand, HMOs are struggling to cope with two other factors," continued Casey. "First is the year-to-year increases in basic healthcare costs attributable to more demand for services by patients. Second is the spiraling expenditures for drugs as new, life-enhancing therapies reach the market.

"HMOs are in an impossible situation. When healthcare costs began increasing in the mid-1990s, HMOs failed to accurately anticipate these increases and build the higher costs into their premiums," explained Casey. "That failure led to the huge losses posted by managed care companies in the 1997-1998 period.

"HMOs are still playing catch-up. Their premium increases are once again approaching double digit levels," he noted. "But this hardly keeps them financially even with the overall

increase in healthcare costs. It leaves the HMOs little or nothing to pass along to providers."

HMO Premium Increases

During the last 30 days, **Foundation Health Systems**, **PacifiCare**, **Cigna**, and **Aetna** each announced premium increases of 8% to 12% for 2001. Casey believes these aggressive price increases will contribute to the decline of HMOs and managed care as we know it today.

"As HMO premiums go up, PPOs become more attractive to both consumers and employers," he said. "Why? Because, for about the same amount of money, PPOs give consumers more choice over their healthcare, while removing employers from potential liability and claims that they restrict care.

"One criticism of closed-panel HMOs is that the patient is denied the ability to shop for the best care and choose the doctor they want," explained Casey. "Who chooses the HMOs for employees? It's the employer. Thus, employers found themselves party to lawsuits filed by patients against HMOs claiming denial of care.

Sizeable Investment Dollars

"Assuming that the premium for a PPO is about the same price as that of a closed panel HMO, employers have plenty of incentive to permit, even encourage, their employees to enroll in PPOs," noted Casey.

"This is one reason why the yearly national rate of increase to HMO enrollment is decreasing while the national rate of increase to PPO enrollment is growing," he added. "Both employers and consumers, faced with the problems of HMOs and higher HMO premiums, are deciding that PPOs represent a valid alternative.

THE DARK REPORT concurs with Michael Casey. It has already published its observations that HMO losses in 1996 and 1997 were due, in a large part, to consumers adding the out-of-plan option during open enrollments in the fall of 1995 and 1996, then using those out-of-plan options during the following year. *(See TDR, February 1, 1999.)*

This was incontrovertible evidence that the middle class American consumer was dissatisfied with the national experiment in closed panel HMOs. More evidence comes from the regular series of announcements by major managed care companies they they are discarding prior approval procedures and scrapping limitations on gatekeeper referrals.

HMOs Morph Into PPOs

What THE DARK REPORT considers notable is Casey's opinion that HMOs will morph into modified PPOs during the next few years. THE DARK REPORT predicts this will be accompanied by a decline in capitated provider reimbursement arrangements for hospitals and physicians.

However, even as physicians and hospitals see more fee-for-service contracts, there will continue to be capitated arrangements for laboratory testing services. As long as laboratories are willing to do capitated deals and try to fill up their unused lab capacity, payers will have little incentive to shift their capitated lab contracts into fee-for-service testing agreements.

Top Service In The Region

As a full-time analyst of the managed care marketplace, Michael Casey's observations and predictions indicate there will be plenty of changes in the way HMOs conduct business.

It remains to be seen, however, whether these changes will be beneficial to clinical laboratories and pathologists. In many regions of the country, the dominant HMO can still dictate terms to providers. **TDR**

Contact Michael Casey at 714-800-1108.

Genesis Clin Laboratory Hits Outreach Home Run

Hospital laboratory outreach sales effort brings in lots of profitable new business

CEO SUMMARY: Commercial laboratory consolidation has left Chicago with only a handful of laboratory providers. New management at MacNeal Hospital's for-profit laboratory division recognized this opportunity. During the past three years, the outreach program was revitalized and the sales force was expanded. The result has been increased revenues and a steady decline in the lab's average cost per test.

IN MANY REGIONS OF THE COUNTRY, consolidation of the commercial laboratory industry has created great opportunities for hospital-based laboratory outreach programs.

Commercial lab consolidation, which occurred through the mid-1990s, fundamentally changed the competitive market for physicians' office testing. Surviving labs cut back services to save money. Many labs operate fewer patient service centers and their lab facilities are often staffed with too few people to properly handle customer service requests.

Genesis Clinical Laboratory, a for-profit division of **MacNeal Hospital**, located in the Chicago suburb of Berwyn, recognized this opportunity. During the past three years, it built an outreach sales and marketing machine that added an additional $6 million per year to outreach sales volume. Genesis has also profitably expanded into markets as far away as Indianapolis.

"In Chicago, we recognized that commercial lab consolidation during the past five or six years had radically altered the competitive marketplace for physicians' office testing," stated Gene Heidt, President of Genesis Clinical Laboratory.

"We saw nothing but opportunity," he continued. "Greater Chicago is a huge market for lab testing services. But, including the two national labs, there exists just a couple of independent labs and hospital outreach programs. We believed that a well-managed lab outreach effort could be both fast-growing and profitable."

Reenergizing The Lab

Heidt was hired in June 1997 to reinvigorate a languishing laboratory organization. "MacNeal Hospital, with 427 beds, is a teaching hospital and tertiary center," explained Heidt. "Before my arrival, its lab division had operated without a senior executive for a number of months. I was given the goal of reenergizing the existing lab outreach program and improving the profit performance of the laboratory.

"I inherited two sales reps and about $11 million per year of outreach business, most of it from nearby physicians who were affiliated with the hospital," said Heidt.

Excellent Case Study

For hospital lab administrators interested in lab outreach, Heidt's business plan and successful implementation provides an excellent case study. He concentrated on internal operations improvement while at the same time ramping up a productive outreach sales and marketing campaign.

"First, it was necessary to replace the two existing sales reps," recalled Heidt. "For lots of reasons, the quality of their new accounts and their sales production was below standards.

"After terminating these two individuals, we hired a sales and marketing manager with a proven track record of high performance," he added. "This new manager was charged with the responsibility for building our sales."

Because of his background in commercial labs, Heidt understands the fundamentals of professional selling and recognizes its importance to the financial stability and success of his hospital-based lab organization.

"It's important that our sales people have the 'right stuff' to succeed" he said. "We've built up our sales force and now have seven sales reps in the field. None had a background in clinical laboratory or pathology when we hired them. But they all had a proven track record of sustained sales production."

Outside Sales Training

To prepare them for clinical lab sales, Genesis provided outside sales training. "Genisis contracted with **Communispond** and their "Socrates Selling Skills program for sales training. Socrates developed an individualized two-day, off-site training program for us.

"Next, we developed a sales compensation plan that pays them only for producing the types of accounts we want," continued Heidt. "For example, we require a monthly average of new account revenues be maintained. Also, we want our sales people to focus on larger accounts, so we don't pay any commission on accounts that bill under $1,000 per month. We pay a healthy commission rate for accounts that exceed $5,000 per month in net revenues."

New clients have signed up at a sustained pace. Heidt says that the opportunity for hospital lab outreach programs to scoop up new business is just as good as it was ten years ago. "The surprise for us is not just that it's a wide-open market, but that all the selling tools used in the late 1980s to bring in new physician clients work just as well today," he said.

Managed Care Issues

Managed care is no longer the factor it was a couple of years ago. "When we sent our first sales reps into the field, **United Healthcare Corporation** had an exclusive capitated contract with **Quest Diagnostics**," said Heidt. "But when United dropped capitation with its provider doctors, it also dropped capitation on its lab services contract. Since then, managed care contracts have not been an issue for us or our new client accounts."

Within the Chicago market, Heidt sees three main selling points that motivate physicians to switch laboratory providers. "First, price is still an issue," he explained. "Illinois remains a client bill state and pricing for lab tests remains an important concern. However, in Indiana, we see less of that. Patient bill seems to predominate.

"Second, physicians are definitely interested in the computer technology offered by their lab provider," noted

Genesis Clinical Laboratory Wants To Advance Its Internet-Based Lab Information Services

"WE SEE HIGH DEMAND BY OUR PHYSICIANS for Internet-based laboratory information services," noted Gene Heidt, President of Genesis Clinical Laboratory.

*"Many of our physician clients are already Web-savvy," he continued. "When we intensified our sales program three years ago, we started putting the ClinScan system into physician offices. On January first of this year, we began to introduce **Advanced Health Technologies'** Dr. Chart to our existing and new clients.*

"Physicians recognize the added value of Web-based lab test ordering and results reporting," Heidt said. "By mid-year, we had generated about $1 million in annual sales volume as a result of Dr. Chart.

"We are aggressively looking for the next generation of Internet lab information products," added Heidt. "It is clearly something we must do to appeal to existing clients and new physician accounts. Also, we can already see how the right ASP product can lower our costs by a significant amount. This will not only come from savings in test ordering and results reporting, but in operational gains due to reduced accessioning labor and similar applications."

Heidt. "This goes beyond simple test ordering and results reporting. The ability of a lab to let the physician study his lab data in a variety of ways is clearly something that appeals to our physician clients.

Doctors "Buy Local"

"Third, we sell on the themes of 'small is better' and 'we're local.' This has great appeal to most physicians, because they want to support local healthcare resources and they've probably had too many unwanted problems from larger, out-of-town labs."

One big change at Genesis Clinical Laboratory is its new owner. **Vanguard Health Systems, Inc.** purchased MacNeal Hospital during the past year. Vanguard, a privately held, for-profit company, was very interested in the profit potential of Genesis' outreach laboratory operations.

"The outreach sales program at Genesis generates two important financial benefits for MacNeal Hospital and our new owners," observed Heidt. "First, our average cost per test for both inpatient and outpatient specimens has been dropping. This is a direct result of economies of scale, as the increased outreach volume hits our lab. Second, our outreach revenues generate operating profits for the hospital. This means we generate extra capital, some of which is available to expand our lab testing services."

Genesis Clinical Laboratory provides an outstanding example of how hospital-based laboratories can develop, and sustain, thriving lab outreach programs. Heidt and his management team understand the importance of a professionally-managed sales force, supported by a well-managed laboratory organization.

New Hospital Owners

In just 36 months, Genesis has added $6 million in annual outreach revenues, grown to seven sales reps, and expanded into neighboring Indiana. The success posted by Genesis is more evidence that hospital laboratories have an inherent competitive advantage over independent commercial labs. It is a reminder that hospital lab administrators are missing a great opportunity to help physicians around their campus while strengthening the capabilities of their lab. TDR

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Technologies to Automate Pap Smear Screening

Market Hesitates to Embrace Automated Screening Products

PART TWO OF A SERIES

BY JOSEPH PLANDOWSKI

EDITOR'S NOTE: This is part two of our three-part series on new Pap smear technology. Guest writer Joseph Plandowski's look at liquid preparation methods for Pap smear testing in his first story gained wide attention and plenty of comments; most were positive.

In this installment, Mr. Plandowski takes a critical look at the first companies to introduce technologies for enhancing or automating aspects of Pap smear screening. His conclusion is that inappropriate business strategies and management missteps have played just as important a role in retarding the acceptance of these technologies as the performance of the products themselves.

CEO SUMMARY: Technology to enhance and improve conventional Pap smear screening was introduced into the clinical marketplace almost five years ago. But the clinical laboratory industry has yet to embrace these various technologies in any meaningful way. Like the introduction of liquid preparation methods for Pap smear testing, these various technologies to enhance and automate Pap smear screening have faced an uphill battle from the beginning. Our guest writer believes that management miscues were among the factors contributing to the business setbacks of the companies offering these technologies.

TECHNOLOGY TO ENHANCE and automate aspects of conventional Pap smear screening has struggled mightily to find widespread acceptance in the healthcare marketplace. Providers and payers have yet to enthusiastically embrace these new products.

In part one of this series, I presented many of the less-publicized issues involving liquid preparation products for Pap smear testing. It is interesting that the recent surge in clinical usage of such products comes despite the absence of an undisputed and compelling equation matching clinical gains against the increased cost of a Pap smear slide prepared with thin layer technology.

This sets up an interesting question. If the added cost of a thin layer Pap smear slide is not offset by compelling and clinically-agreed upon performance benefits, then why is usage of thin layer Pap smear preparation kits increasing, while technology to automate and improve conventional Pap smear testing languishes?

This is precisely the question which stimulates so much heated debate among *knowledgeable* professionals representing the gynecology profession, the health insurance industry, government health programs, clinical laboratories, and pathologists. If cost-benefit equations were compelling, there would be a much higher degree of consensus among all the parties with a vested interest in Pap smear screening.

Several things must occur for new diagnostic technology to replace and supplant tried and true clinical procedures. First, in today's managed healthcare environment, there must be *clear and compelling* clinical evidence that the new technology does improve healthcare and patient outcomes. Payers and government health programs refuse to reimburse for "maybe" technology.

Second, there must be an economic justification for using new technology in clinical applications. Can the added cost of new technology be justified when compared to its clinical benefits? This is the specific argument that generates the most passion whenever the topic of thin layer Pap smear preparation is discussed.

Critical To Success

Third, the ability of a company's management to competently develop and introduce a new lab test technology into the marketplace is as critical to success as the technology's ratio of clinical benefit versus economic cost.

These three critical success factors apply to any type of new cervical cancer screening technology. To date, four companies have made serious efforts to automate some aspect of conventional Pap smear screening.

In 1995, **Neuromedical Systems, Inc.**, (PapNet® System) and **NeoPath, Inc.** (AutoPap® System) were first to gain FDA approval to bring their cervical cancer screening products to market. **AutoCyte, Inc.** (SCREEN®) and **MorphoMetrix, Inc.** (Cymet™) have had cervical cancer screening products in either the development phase or pending FDA approval.

Since 1995, all four of these companies have met unexpected obstacles. One

company filed bankruptcy and ceased operations. Two of these companies merged. The fourth has decided to apply its technology in areas of diagnostics other than Pap smear screening.

Filed Bankruptcy

Let's begin with Neuromedical Systems, Inc. (NSI), which filed Chapter 7 bankruptcy in February 1999 and ceased operations. A variety of factors contributed to the collapse of NSI. *(See TDR, April 5, 1999.)*

Its PapNet system had been approved by the FDA as an adjunctive test in 1995. Basically, this meant that every woman needed to have the conventional Pap smear test performed. If she wanted, she could pay extra, out of pocket, to have the PapNet procedure. The FDA approval limited the way NSI could market the test to clinical laboratories, physicians, payers, and patients.

Another element of NSI's PapNet system was the way the technology operated. Once a conventional Pap smear slide was prepared, the PapNet system would scan the slide and run the data through a neural network software system. This software would select 128 cells that it considered to be the most suspect. Even if a particular Pap smear was normal, PapNet would still select 128 cells for review. This was a function of the way the neural net software processed the data.

Cumbersome Procedure

The workflow process to perform an adjunctive PapNet procedure was cumbersome and time consuming for clinical laboratories. After screening the conventional Pap smear slide in the normal manner, participating laboratories would need to forward that slide, via overnight delivery, to NSI's PapNet screening center in Suffern, New York.

At NSI's lab, the slide would be scanned and the data processed by the PapNet system. The slide and a diskette with the data were returned, via overnight delivery, to the originating laboratory. Next, a cytotech would review the PapNet selection of 128 suspect cells on a $9,000 reviewing station that had to be purchased from NSI.

NSI suggested that labs charge women $35 to $40 for the adjunctive Pap smear procedure. NSI charged labs about $18 to scan the slide on PapNet. Most labs also had to pay for packing materials and shipping charges. It generally took in excess of a week to get the slide to NSI and back to the originating lab, during which time the final diagnostic report was delayed.

This was a complex workflow process. Clinical studies of PapNet yielded mixed results. Any benefits from increased sensitivity were outweighed by the economics of the PapNet process, including having a cytotech review 128 cells for every slide that was normal.

Since 1995, all four of these companies have met unexpected obstacles

One clinical trial, reported in *ACTA Cytologica* (1998:42:265-270) and noted in the December 1998 issue of *CAP Today*, seeded 195 abnormal slides into 20,000 normal slides. All the slides were screened on PapNet. Only 44% of the seeded slides were recognized as abnormal.

Co-author of the study, Gabriele Medley, M.D., Director of the **Victoria Cytology Service**, Victoria, Australia said "The bottom line is that this particular technology, at the time we tested it, did offer something additional, but it was not a guarantee." In response, Laurie Mango, M.D., Chief Medical Officer at NSI stated "These results *were not disappointing to us* (my italics). We only claim increased sensitivi-

ty. Nobody has a system that finds the majority of false negative cases."

Most laboratorians are also aware of NSI's ill-fated marketing effort. The company ran a high profile, direct-to-consumer ad campaign in publications like *Newsweek*, *Time*, *Glamour*, *Good Housekeeping*, etc. that informed women about the deficiencies of conventional Pap smear screening. The ads directed them to demand a PapNet test when they visited their doctor. This ad campaign aggravated many physicians, who found themselves having to defend the clinical effectiveness of conventional Pap smears with their upset patients.

Neuromedical Systems' strategic business plan was a loser from the start. It took the company only four years to run through the $135 million it raised in its 1995 IPO. Annual sales never exceeded $10 million per year worldwide.

When NSI went bankrupt earlier this year, AutoCyte snapped up the intellectual property and patent estate. AutoCyte paid the bankruptcy court about $14 million in cash and stock. That seems to be the end of the PapNet system. AutoCyte has shown no interest in continuing to support the product.

FDA Clears AutoPap

NeoPath, Inc. of Redmond, Washington entered the clinical marketplace about the the same time as NSI. NeoPath's AutoPap 300 QC received FDA clearance in September 1995 and was limited to quality control screening of Pap smears.

From the start, NeoPath's business strategy was to meet the needs of labs doing high volumes of conventional Pap smears. As a QC test, the improved accuracy of AutoPap was expected to cut malpractice-related costs enough to justify using it. Additionally, the AutoPap received approval from HCFA to replace the mandated practice of manual QC under CLIA requirements.

NeoPath then expected that, based on actual clinical performance, the FDA would approve AutoPap as a primary screening device. This occurred in May 1998, when the AutoPap System received FDA clearance for primary screening. This should have been the "Holy Grail"—a way for cytology labs to automate one of the last frontiers in the laboratory! So why hasn't this technology been universally adopted?

Automated Screening

NeoPath's initial two products were automated screening systems that integrate proprietary high-speed image processing computers, video imaging technology, and sophisticated image interpretation software to capture and analyze thousands of microscopic images from a Pap smear.

The AutoPap 300 QC product is a quality control device for Pap smears screened by cytotechnologists and diagnosed as "Within Normal Limits (WNL)."

As currently approved by the FDA, the AutoPap Primary Screening System product is a primary screener that allows as many as 25% of the slides processed by the product to be diagnosed as WNL without any further review by cytotechnologists. The remaining 75% must be manually screened. The AutoPap System contains upgraded software features allowing it to also perform primary screening. It has replaced the AutoPap 300 QC.

Five Important Issues

Five issues are important to note with these products. First, both products are restricted to the use of glass coverslips, not plastic coverslips that many laboratories use. Second, the products cannot be used to replace a laboratory's current practice regarding the rescreening of Pap smears from "risk"

patients. Patients flagged on Pap test requisitions as "risk" patients must be manually screened.

Cannot Use Liquid Prep

Third, the products are restricted to conventionally prepared Pap smears. As yet, they cannot be used with liquid based preparation technologies, such as Cytyc's ThinPrep or TriPath's PREP. Fourth, neither product is supplied with software to interface with any laboratory information system (LIS), such as **SunQuest** or **Antrim**. Fifth, 15% of the slides put through the AutoPap System must be rescreened manually for QC purposes versus only 10% of slides manually screened.

NeoPath's revenues and losses present a dismal picture. Revenues grew from $3.1 million in 1996 to $12.1 million in 1998. Net losses throughout these years were huge. In 1996, the net loss was $17.7 million. The loss grew to $23.6 million in 1997 followed by a loss of $26.2 million in 1998.

A significant portion of NeoPath's sales were concentrated among a relatively small number of customers. To that point, at the end of 1998, **SmithKline Beecham Clinical Laboratories** (SBCL) and **Unilab, Inc.** had about two-thirds of all the units NeoPath placed.

Quest-Cytyc Agreement

In the second quarter of 1997, Cytyc entered an agreement with **Quest Diagnostics Incorporated** to provide the ThinPrep System for PAP testing. This was an exclusive agreement whereby Quest Diagnostics would not provide other liquid-based thinlayer sample preparation technologies unless FDA claims for such products exceeded claims for the ThinPrep System.

Further, and very importantly as outlined in the agreement, Quest Diagnostics would only provide computer aided rescreening *upon customer initiated request!* This meant Quest Diagnostic would not promote NeoPath's automated screening of Paps.

That limitation became more than an interesting fact when Quest Diagnostics acquired SBCL in August 1999. SBCL was committed to actively promoting NeoPath's AutoPap System but not Cytyc's ThinPrep System. Previously, client-ordered ThinPrep Paps were sent outside the SBCL network.

As with NSI, weep for NeoPath shareholders. A $100 investment in NeoPath on the initial public offering (IPO) date in January 1995 was worth about $36 in mid-June 1999.

Like NSI, NeoPath raised a considerable amount of money. More than $103 million was raised from investors and others between 1995 and 1998. Like NSI, it took NPTH only four years to spend most of that investment.

AutoCyte's Business Plan

This brings us to the AutoCyte, Inc., based in Burlington, North Carolina. AutoCyte was organized around the goal of developing an integrated system of instruments for automating Pap smear screening and other cytology procedures. Its PREP system for liquid preparation of Pap smears gained FDA approval in 1999. Its SCREEN system would have competed with NeoPath's AutoPap Primary Screen System.

However, negative cash flow at AutoCyte, Inc. was a major factor in its merger with NeoPath, Inc. to form **TriPath Imaging, Inc.** in October, 1999.

This merger revised the business plans of both companies. As a merged company, TriPath could pool the patents and technologies for imaging and processing Pap smear slides from Neopath, Neuromedical Systems, and AutoCyte. It later bought patents from **B-D's Cell Analysis Systems.**

The new goal has been to marry TriPath's PREP system with the Auto-

Automated Microscope Workstations Prove a Bust

THERE WERE ALSO EFFORTS to automate microscope workstations for cytotechnologists. NeoPath offered a product called Pathfinder. **Accumed International, Inc.** had a product called AcCell 2000.

The primary feature of both products was a computerized motor on the microscope stage which would move the slide and present 100% of the cells to the cytotechnologist. This was to ensure that the cytotechnologist viewed all the cells on every Pap smear slide. The AcCell product attached a computer to the microscope which could offer a variety of features, including marking cell locations and tracking the productivity of individual cytotechnologists,

Neither product made any dent in the clinical marketplace. Essentially, these automated microscope stages forced cytotechs to alter their preferred method for reading a Pap smear. They also showed the weaknesses in how individual cytotechs processed their daily flow of Pap smear slides.

NeoPath terminated Pathfinder sales and wrote off the program. AccuMed exited the business completely in 1999.

Pap primary screening system, then gain FDA approval to sell them either individually or as an integrated system. However, in the year since the merger, TriPath has not provided an estimated date as to when its combined automated slide preparation and screening module would obtain FDA approval and be ready for market.

Another firm was committed to developing an automated screening instrument for Pap smear testing. It is MorphoMetrix, Inc. of Toronto, Canada. MorphoMetrix, probably after watching the experience of NSI, NeoPath, and AutoCyte, has redirected its research into other clinical areas.

The efforts to automate various aspects of Pap smear testing by Neuromedical Systems, NeoPath, AutoCyte, MorphoMetrix, and AccuMed have yet to find widespread acceptance in the clinical marketplace. This fact demonstrates the gap between clinical effectiveness and added cost of the new technologies.

At this stage in the market evolution, only TriPath Imaging has an approved automated screening system available in the United States and internationally. Its AutoPap system has a sizable, happy customer in **Unilab.** It had another major customer in SmithKline Beecham Clinical Laboratories, until Quest Diagnostics acquired the company.

Recently **Laboratory Corporation of America** announced a contract to install AutoPap systems throughout its national network of regional labs. As these AutoPaps become operational, they may help TriPath gain additional revenues from other laboratories.

Effectiveness Versus Cost

The experience of these companies since 1995 demonstrates that, although technology may be capable of improving specific aspects of conventional Pap smear testing, there must be a clear, measurable cost-versus-benefit gain to the healthcare system for automated Pap smear screening products to catch on. TDR

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COMING: PART THREE: Methods clinical laboratories should use to calculate the true costs of acquiring and using the various new Pap smear technologies.

Internet Developments

Predict Steady Decline In Fees For Web-Based Lab Information

EVEN THOUGH WEB-BASED LAB TEST ordering and results reporting is in its infancy, the free market already seems to be driving prices down.

Late in 1999, **Healtheon/WebMD, Inc.** was reportedly signing contracts to provide Web-based information services for fees ranging between 60¢ and 75¢ per patient (for order and test on the same patient).

Aggressive Sales Campaign

Healtheon/WebMD mounted an aggressive sales and marketing campaign to sign up big laboratory companies. It succeeded in getting signed agreements with **Laboratory Corporation of America, Inc.**, **DIANON Systems, Inc.**, and **UroCor, Inc.** by last December. *(See TDR, November 1, 1999.)*

Despite this early head start in the marketplace, as of this summer, THE DARK REPORT is unaware of any clinical laboratory using Healtheon/WebMD's Dx product in a thin client–Web browser accessed mode.

Certainly part of the delay in Healtheon/WebMD getting some of these clients operational has to do with its well-publicized operational problems. The rapid pace of acquisitions has created major challenges at the healthcare e-commerce giant.

But another factor in the delay may be that Healtheon/WebMD's first laboratory clients are watching the pricing from competing vendors of thin client–Web browser accessed lab info products. They don't want to go forward until they have comparable deals.

For example, when **Centrex Clinical Laboratories** installed the **Abaton.com** product in January, Chief Information Officer Lee Barnard told THE DARK REPORT that the expected cost of thin client–Web browser enabled lab test ordering and results reporting would be less than 40¢ per patient. That is half as expensive as Healtheon/WebMD's target pricing. *(See TDR, February 14, 2000.)*

An even newer entrant into the marketplace is **LabPortal.com**, based in Chantilly, Virginia. It is launching its ASP-based lab information product. It has several different pricing models. For example, one pricing model it uses is based on the lab paying a monthly service fee. The service fee is based on the number of individual physicians who have passwords to access the system for ordering tests and receiving lab results.

Striking Difference

The speed at which the price for thin client solutions for Internet-enabled lab test ordering and results reporting is falling should not surprise lab executives and pathologists. The Internet is a productivity tool which makes the transmission of information both instantaneous and virtually costless.

Further, thin client, ASP-based lab information services is such a radical new way to conduct business that there is probably no way to accurately predict how clinical laboratories will actually use this new tool. TDR

Lab Industry Briefs

EMERGING BUSINESS OPPORTUNITY IN TISSUE BANKS & CANCER DATA

EVEN AS THE HEALTHCARE SYSTEM squeezes pathologist incomes in a variety of specific professional services, it opens up business opportunities in other segments of the pathology field.

Researchers and pharmaceutical companies want clinical data on cancer cases. They also have a need to evaluate a wide range of tissue specimens as part of their research studies. Combined, the demand for these products is fueling a growing market in anatomic pathology information and tissue banking.

The most aggressive pathology companies, those which are publicly-traded, recognize this developing business opportunity. They are moving swiftly to sign contracts and generate revenues from selling such services.

In the case of **IMPATH, Inc.**, it announced an agreement with **Millennium Pharmaceuticals, Inc.** in July to cooperate with Millennium's product development activities. The agreement calls for IMPATH to utilize its cancerous tissue samples and clinical data information products to assist Millennium's research into oncology therapeutics and predictive medicine products.

IMPATH currently has 585,000 analyzed cancer cases in its clinical repository. It is adding about 150,000 new cases per year to its database.

AmeriPath, Inc. is also moving to capitalize on the demand for cancer data and tissue specimens. It formed an alliance with **Genomics Collaborative, Inc.**, of Cambridge, Massachusetts. AmeriPath will provide "samples from normal, diseased, and cancerous tissue to researchers in industry and academic laboratories."

Genomics Collaborative is a company specifically formed to develop tissue banks. It wants to create working relationships with pathology group practices around the country to help them develop tissue banking capability.

According to Ken Bottles, M.D., President at Genomics Collaborative, his company predicts that increasing demand for tissue specimens by researchers will create an opportunity for even small pathology groups to generate revenue from tissue banking activities.

THE DARK REPORT observes that pathologists seeking diversified income and revenue growth opportunities should evaluate the potential of pathology information products and tissue banking. These are the types of complementary services that can supplement revenue from professional pathology services.

DRUGS OF ABUSE TESTING LABS DEVELOPING NEW PROFIT CENTERS

SUSTAINED COMPETITION for drugs of abuse (DOA) testing clients has driven prices down and made many high volume accounts unprofitable to lab providers.

In reaction to that development, a number of specialty DOA lab companies are looking for ways to leverage their primary relationship with commercial accounts into new profit streams. The Internet figures prominently in this effort.

At **PharmChem Laboratories, Inc.**, the company has developed an ASP-based (application service provider) information service for its drugs of abuse testing clients. Using

thin client technology, PharmChem has created a seamless information link between it, client companies, and independent medical review officers.

PharmChem President Joseph Halligen told THE DARK REPORT on a recent site visit that its ASP-based information management strategy has the potential to generate more profit per transaction than doing the actual laboratory tests.

At **MedTox Scientific, Inc.** in St. Paul, Minnesota, the business strategy is to expand into logistics management. Earlier this month, MedTox purchased a client list for collection services in the Bloomington area. This purchase is expected to double its collection volume at that site.

Lab*One*, Inc., based in Lenexa, Kansas, signed an agreement with an e-commerce start-up, **eScreen, Inc.** to provide testing services. eScreen, a division of **National Medical Review Offices, Inc.**, manages the drug testing programs for business clients and is one of the nation's largest medical officer review service firms.

CARESIDE GOES NAVY IN DEMONSTRATION OF ROUTINE POC TESTING

HERE'S AN INTERESTING DEVELOPMENT. The **United States Navy** will place **CARESIDE, Inc.'s** chemistry and hematology point-of-care instruments on a Navy support ship.

The objective is to evaluate the performance of the CARESIDE Analyzer® and H-2000 Hematology units aboard ship, in a dynamic environment. The study is tied to a fixed number of patients.

The ship is part of the Navy's Military Sealift Command's Naval Fleet Auxiliary Force (NFAF). This is the group which is responsible for providing logistical support to naval operations. It maintains ocean tugs, oilers, ammunition ships, combat ships, and two hospital ships.

The United States military has a keen interest in various forms of emerging point-of-care diagnostic testing technology. THE DARK REPORT is aware that one branch of the military is also evaluating **Luminex Corporation's** LabMap® testing system for point-of-care and battlefield applications.

Military evaluations involving products from CARESIDE and Luminex are evidence that the armed forces believe these technology platforms may, with reasonable investments, enable diagnostic testing to occur outside a core laboratory. Having point-of-care diagnostic capability is a major goal of the medical services for the armed forces.

LAB PRODUCTS INVOLVED IN INTERNET E-COMMERCE VENTURE

WATCH FOR THE EARLIEST BUSINESS activities of the new electronic health exchange soon to be formed by **Fisher Scientific, Inc.**, **McKesson HBOC, Inc.**, **Cardinal Health, Inc.**, and **AmeriSource Health Corporation**.

The companies signed a definitive agreement to create the joint venture. It has not yet been named, but will be an independent company located in Minneapolis, Minnesota. It will be an Internet-based, business-to-business electronic health exchange, offering products to hospitals, physicians, laboratories and other healthcare firms.

Fisher Scientific's participation is notable. Fisher's Web site has earned praise as one of the best-organized healthcare distributor sites now operating. A steadily increasing number of Fisher's customers, including clinical laboratories, are using its Web site to order products. TDR

INTELLIGENCE

LATE & LATENT
Items too late to print, too early to report

Bio-Reference Laboratories, Inc. (BRLI) announced that its physician Web portal service, CareEvolve.com, gained 200 enrolled physicians in the first eight days following its August 1, 2000 release. As a laboratory company, BRLI recognizes that its physician network is the real asset in today's world of healthcare informatics. CareEvolve.com is BRLI CEO Dr. Mark Grodman's answer to protecting the laboratory's turf from incursions by the multitude of healthcare e-commerce start-ups.

ADD TO: BIO-REFERENCE

As a laboratory, Bio-Reference's Internet strategy sets it apart from all other clinical labs in the United States. *(See TDR, May 30, 2000.)* Its physician Web portal not only links the lab to the doctor for lab test ordering and results reporting, but offers the doctor a full menu of services, including his own Web site, ISP, electronic payer enrollment, claims submission, etc. Best of all for the lab, the physician pays BRLI a monthly fee for these services!

MOTOROLA TO ENTER BIOCHIP MARKET BY YEAR'S END

Motorola Inc. signed an agreement last Thursday to use **Incyte Genomics Inc.'s** gene-patent portfolio and gene-sequence databases in its biochips. Motorola wants to commercialize biochips that feature DNA bioarrays. The business plan is to offer these biochips to pharmaceutical companies, as well as independent researchers in hospitals and universities. Nicholas Naclerio, Vice President and General Manager of **Motorola BioChip Systems**, predicted that, within as little as five years, "you will be able to go into a doctor's office and be tested. You will be able to determine if an infection you have is drug-resistant or not and potentially be screened for cancer."

MORE ON: MOTOROLA

Motorola predicts that it will have DNA biochips ready for sale later this year. It shows the explosive speed with which genomic technology will hit the healthcare marketplace. IBM announced last Wednesday that it would invest $100 million into life sciences and genomic-based applications. IBM predicts that the $3.5 billion spent this year in the life sciences technology market will grow to $9 billion in 2003! Motorola's biochips are intended to compete with **Affymetrix's** biochips. The fact that Motorola will sell biochips in the healthcare marketplace demonstrates that chip technology will soon become as common in healthcare as it is in today's telecommunications and consumer devices. This means the day of the "lab on a chip" will arrive much sooner than most laboratorians expect.

EXECUTIVE WAR COLLEGE GAINS NOTICE

Clients and regular readers of THE DARK REPORT may want to read the story about this year's EXECUTIVE WAR COLLEGE that appeared in the July issue of *MLO Magazine*. Editor Darlene Berger did a detailed story about the events at this year's program. *MLO Magazine* is the first major lab industry publication to do an in-depth analysis of our annual EXECUTIVE WAR COLLEGE on laboratory and pathology management.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 11, 2000.

THE DARK REPORT

UPCOMING...

- *The Dark Report's Annual Ranking of National and Esoteric Testing Labs.*
- *An Inside Look at the Business Strategies Used to Build a Hospital Core Lab into a Regional Powerhouse.*
- *Update on Hospital Pathology Part A Contract Trends.*
- *Luminex Moves Rapidly to Bring Multiplexed Bioassays to Lab Marketplace.*