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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

When Managers Make Decisions

IF YOU OPERATE A CLINICAL LABORATORY, does the news of **NeoPath, Inc.'s** national contracts with **Kaiser Permanente** and **SmithKline Beecham Clinical Laboratories** (SBCL) alter your competitive position in the market?

After all, it's only been a few months since the **Food and Drug Administration** (FDA) approved NeoPath's Pre-Market Application (PMA) to use its AutoPap System as a primary screener. AutoPap has not been in widespread use as a primary screener. Consequently, any laboratory interested in acquiring this system has only a finite amount of clinical data available to evaluate this product.

So why did Kaiser make the decision to utilize AutoPap as the primary screener for its yearly volume of 1.4 million Pap smears? What did SBCL know that encouraged it to adopt AutoPap for primary screening of its yearly volume of Pap smears?

I would suggest that these decisions are not based on unique knowledge, unavailable to other laboratories. Quite the contrary. I believe these two companies demonstrate why people make the difference between success and failure within any laboratory company. Managers at both Kaiser and SBCL took initiative to bring the technology in-house at a time when it was exotic, unknown, and unproven.

Management at both companies encouraged their people to experiment with the earliest generations of competing automated cytology instruments. Corporate learning occurred as a result of the hands-on interaction with various new methods for screening Pap smears. These organizations supported management "experiments" that held the promise of improved quality and increased productivity.

I offer another insight about these two companies. It is risky to be the first to adopt radical new technology and clinical methods. But reward is commensurate with risk. Managers took the "risk" to be first. But how much risk are they taking after they have their *own* clinical experience with this automated cytology technology? Their willingness to experiment gave them knowledge unavailable to competing labs.

Managers and Medical Directors at both these companies should get recognition for their willingness to change the status quo. Their actions will improve the competitive position of their companies, possibly even while putting your own laboratory at a competitive disadvantage! **TDR**

Kaiser, SBCL To Automate Pap Smear Screening

NeoPath's AutoPap screen system chosen in move to improve quality and productivity

CEO SUMMARY: Two of the country's largest Pap screen testing organizations are preparing to introduce automated primary screening into their laboratories. NeoPath's contracts with SmithKline Beecham Clinical Laboratories and Kaiser Permanente mark the beginning of a new market cycle. NeoPath is poised to exploit these developments while continuing to enhance AutoPap's capabilities.

TWO OF HEALTHCARE'S LARGEST players announced their intention to acquire **NeoPath, Inc.'s** AutoPap® Primary Screener for widespread use in Pap smear screening.

SmithKline Beecham Clinical Laboratories (SBCL) and **Kaiser Permanente** are each contracting to acquire AutoPap Systems. Both companies intend to move 100% of their Pap smear screening to AutoPap technology during the next 24 to 48 months.

This is a significant development. Of the 55 million Pap smears done annually in the United States, SBCL does about 5.5 million and Kaiser processes over 1.4 million. With these two contracts alone, NeoPath will capture 12.5% of the national Pap smear market.

"From a business viewpoint, each company is acquiring AutoPap Systems for somewhat different reasons," said NeoPath's President, CEO and Chairman, Alan Nelson, Ph.D. "For Kaiser, AutoPap primary screening will be incorporated as its standard-of-care for cervical cancer screening. As an integrated healthcare system, Kaiser is keenly interested in improved clinical outcomes which the AutoPap Primary Screening System delivers over the life of their patients.

"SBCL is a commercial laboratory," he continued. "Unlike Kaiser, it may not get Pap smears from the same patient over a multi-year period. For that reason, the AutoPap's demonstrated improvement in specificity and sensitivity is an important benefit for them.

"Besides the clinical benefits, both companies are moving to AutoPap primary screening because it also offers

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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).

operational efficiencies and capacity improvements," added Dr. Nelson.

Clients of THE DARK REPORT should recognize the significance of these events. Two of the nation's more respected healthcare organizations are making an unqualified decision to adopt NeoPath's AutoPap Primary Screening System as the cornerstone of their cytology programs.

Currently everything in cytology and pathology is manual. Practitioners sometimes write on the slide itself with a pencil. Many laboratories work with pen and paper to start the process of producing a report.

Executives at these companies tell THE DARK REPORT that clinical experience with the AutoPap QC System and the AutoPap Primary Screening System provided unambiguous data. The product delivers worthwhile clinical benefits in a cost-effective manner.

With upwards of seven million Pap smears per year funneling through these two companies, NeoPath's automated cytology technology is about to transform the Pap smear industry. The influence of AutoPap will extend beyond simply a clinical and cost benefit contribution. It will impact information and outcomes studies. This potential for NeoPath's technology has been overlooked by most pathologists and laboratory executives.

"NeoPath has big plans in the area of information management," stated Dr. Nelson. "Currently everything in cytology and pathology is manual. Practitioners sometimes write on the slide itself with a pencil. Many laboratories work with pen and paper to start the process of producing a report.

"We designed our technology to act as a data node," he continued. "For the first time, diagnostic cellular information can be captured and entered into the electronic patient record. Prior to this, the only effective way to retain useful cellular information on a particular patient was to archive the slide itself.

"AutoPap is the only Pap smear screening engine which produces data," noted Dr. Nelson. "AutoPap is a precise analytical device that measures critical parameters heretofore unobtainable by conventional methods."

Explicit Measurements

"AutoPap's software algorithms operate from explicit quantitative measurements. This differs from a neural network software program," explained Dr. Nelson. "Unlike neural network software, AutoPap's algorithms function like a ruler or caliper. This makes it possible to objectively analyze data, then refine the algorithms to give them increased accuracy. It is a process where additional case data can contribute to improvement in the algorithms."

As clinical practices are moving toward an integrated model, the data capture feature of AutoPap is a distinct advantage. Integrated clinical practices will increasingly demand that individual data sets from lab tests, Pap smears, and clinical observations of the patient be merged into a comprehensive outcomes study. NeoPath's AutoPap has the capability to produce and deliver that data.

Complementary Product

Another product which NeoPath is developing will support the AutoPap Primary Screen System. It is NeoPath's Pathfinder Microscope Station.

"Once AutoPap identifies the 25% of the slides which are normal and need no further review, it refers the other 75% of the slides to cytotechs. AutoPap provides the cytotechs with a ranking of those slides by potential for abnormality," said Dr. Nelson. "Once AutoPap maps the Pap smear, the Pathfinder will

ultimately be designed to receive these coordinates and guide the cytotech to the cells needing scrutiny.

"Cytotechnologists will continue to be an integral part of the Pap smear screening process," said Dr. Nelson. "As a primary screener, AutoPap still requires close attention and involvement by cytotechs and pathologists. The Pathfinder system is designed to increase the accuracy and effectiveness of cytotechs and pathologists by allowing them to use information generated by AutoPap."

Reimbursement A Challenge

For NeoPath, winning contracts with SBCL and Kaiser Permanente is a major boost for the AutoPap technology. This escalating utilization will help drive reimbursement for automated cytology, which remains a challenge. Until a satisfactory level of reimbursement for automated cytology CPT codes is established, many clinical laboratories might defer a decision on acquiring this technology.

THE DARK REPORT believes this issue will not hinder the acceptance of AutoPap as a primary screener. Use of the AutoPap in real commercial laboratory settings is providing real data about two benefits which address the issue of "added cost."

First, because AutoPap can screen up to 25% of the slides into a "no review" category, laboratories have two productivity options. Assume that a laboratory is staffed to handle 100,000 Pap smears per year and it acquires AutoPap for primary screening.

In option A, the lab can chose to redirect staffing by 25% (100,000 slides, less 25,000 "no review" slides leaves 75,000 slides to be screened manually).

In option B, the lab can use the existing cytotech staffing to screen additional slides. Assume 133,333 slides per year, less 33,333 (25%) "no review" slides leaves 100,000 slides to be screened manually, consistent with the lab's current staffing head count.

Combine this increase in laboratory productivity and test volume with improvement in diagnostic accuracy, and the economic and clinical impact to operate AutoPap as a primary screener makes the technology attractive and cost-effective. Both SBCL and Kaiser are investing their money based upon this conclusion. **TDR**

(For further information, contact Alan Nelson, Ph.D. at: 206-867-2422.)

Reimbursement Still To Be Determined

*For 1999, the **American Medical Association** is adding new CPT codes to address automated primary Pap smear screening.*

NeoPath announced that codes 88147 and 878148 will apply to the AutoPap Primary Screening System. Effective January 1, 1999, codes and code descripters become effective for billing and reporting.

NeoPath, recognizing that reimbursement for these procedures is of vital interest to clinical laboratories, recently created a reimbursement SWAT team of six people to work with laboratories and payers throughout the country.

It is still uncertain where reimbursement levels for AutoPap primary screening will settle. There is demonstrated improvement in AutoPap primary screening procedures. However, manual Pap smears have historically been reimbursed at very low rates relative to the true cost of performing the test. Issues involving improved patient access may also favorably affect the eventual reimbursement amount for AutoPap's primary screening procedures.

Automated Cytology Update

Kaiser Plans Widespread Use For Pap Technology

Actual clinical experience with AutoPap System in QC and primary screening proves encouraging

WITHIN THE HMO INDUSTRY, **Kaiser Permanente** is highly respected for its thorough research into the clinical efficacy and economic cost of new healthcare technologies.

That is the reason why Kaiser's decision to adopt **NeoPath, Inc.'s** automated cytology technology for primary screening of Pap smears is getting widespread attention within the laboratory community.

Coupled with a similar decision by **SmithKline Beecham Clinical Laboratories** (SCBL), the clinical and the competitive environment for Pap smear testing is shifting in fundamental ways.

Moreover, Kaiser has a different relationship to patients than a commercial laboratory like SmithKline. Kaiser is a closed HMO and truly offers "cradle to grave" care for its beneficiaries. As the largest non-profit HMO in the United States, it does over 1.4 million Pap smears per year just inside its own system.

Early Detection

Because Kaiser has total responsibility for a beneficiary's health, it is motivated to spend money on early detection which could reduce downstream costs. It will offer preventive tests that government and other private health plans may not currently pay for. More importantly, it is constantly looking for ways to simultaneously improve healthcare outcomes while lowering the overall cost of care.

Curious about what Kaiser might know about this technology that would be useful to clients of THE DARK REPORT, an exclusive interview was arranged with Gene Pawlick, M.D., Director, Regional Laboratory for Kaiser Permanente-Northern California.

New Discoveries

Dr. Pawlick is an active participant in Kaiser's various evaluations of different automated cytology technologies. "Kaiser is keenly interested in new discoveries which promise to improve current cytology practices," said Dr. Pawlick. "For that reason, we have participated in many clinical studies and trials for the various automated cytology technologies.

"Kaiser-Northern California did a joint study with Kaiser-Southern California soon after the FDA approval in 1995 of NeoPath's system for quality control," he noted. "We were impressed with its performance. We asked to be a field site in the clinical studies needed to support NeoPath's FDA application for approval as a primary screener.

"For that reason, we have a lot of direct clinical experience with this instrument," continued Dr. Pawlick. "NeoPath's automated primary screen-

ing system has increased the sensitivity of the Pap smear screening process. The published clinical studies in which we participated document the specific levels of improvement we experienced within the Kaiser laboratories.

"In fact, the increased sensitivity came thundering out of the laboratory at us," he added. "No one could ignore it. The science was beautiful and the impact on patient care was obvious."

Technology Standard

"That is why we have chosen NeoPath as our technology standard at the program-wide level," said Dr. Pawlick. "The details on a national purchasing contract have been hammered out and the plan is for all Kaiser operations to convert their Pap smear screening to this technology within 24 months.

"In the meantime, we are beginning to share the clinical information with our physicians," noted Dr. Pawlick. "Across the Kaiser system, the gynecological community is interested in a more sensitive technology which can improve early detection."

Technology Was Coming

As at SBCL, cytotechnologists within the Kaiser laboratories greeted the AutoPap Systems with some apprehension. "Realistically, most cytotechs have watched the development of various Pap smear products during the last six years. Everyone knew it was coming," observed Dr. Pawlick. "What many cytotechs did not anticipate was that professional skills are needed to keep these instruments operating accurately.

"This is not like a toaster, where you buy it, bring it home, and you can turn the dial to make the toast light or dark," he explained. "These instruments require cytotechs who understand how the machine operates, understand cytology, and apply both skills to keep the instrument finely-tuned.

"In fact, I predict that cytotechs who embrace this technology and learn to blend their cytology skills with the machine's capability will have tremendous career opportunities that don't exist today," added Dr. Pawlick. "Everyone here is still learning what these instruments can do and how they require interaction with cytotechs to maximize the sensitivity and specificity, whether screened automatically or manually."

Liquid Prep: Is The Jury Still Out?

Along with NeoPath's AutoPap QC and Primary Screening Systems, there is another emerging cytology product. It is Cytyc Corporation's ThinPrep® monolayer system.

During THE DARK REPORT'S interviews with executives at Kaiser Permanente and SBCL, there was little discussion pro or con about ThinPrep or other liquid monolayer Pap smear preparation products.

The key question which surrounds the monolayer Pap smear is cost versus clinical benefit. This was addressed in the Blue Cross/Blue Shield study of new cytology technology, which concluded that monolayer Pap smears did not offer a sufficient clinical improvement for the additional cost, given its current technology.

Certainly Kaiser and SBCL have made strategic decisions to pursue automated screening on a system-wide basis before adopting monolayer preparation products across their national organizations. It may be that monolayer preparation technolo-gy will evolve on the heels of automated screening.

If that proves to be true, then today's generation of monolayer preparation technology is possibly still somewhat ahead of its time.

For an organization built upon data, exhaustive research, and frequent clinical studies, the ability of NeoPath's instrument to electronically capture data, process it and store it has not gone unnoticed at Kaiser.

Information Capability

"There are two aspects to AutoPap's data and information capability which excite me," said Dr. Pawlick. "First, its artificial intelligence can be improved over time. That means we can continually raise the bar over current standards of practice. If the instrument delivers in this area, there should be substantial clinical benefit, accompanied by worthwhile reductions in the cost of care.

"Second, we in Northern California want to create a data base of our own patient population," he explained. "As a cervical pathology subspecialist, I would love to capture more than just the diagnosis. I believe that if we could look at more detailed clinical information and match that against other clinical data, it would result in some very worthwhile discoveries."

Collectively, Dr. Pawlick's comments indicate that Kaiser Permanente found the clinical benefits to be, as he put it, "impressive." As with SBCL, Kaiser found further validation about AutoPap's cost effectiveness in the **Blue Cross/Blue Shield** study released last April.

Kaiser, as a non-profit HMO, has a different business mindset than SBCL, which is a for-profit commercial laboratory. But both organizations tell a consistent story about significant improvement in sensitivity and specificity. Each acknowledges a certain level of operational benefits also expected from NeoPath's automated primary screening technology.

Willing To Move Ahead

It is a strong endorsement for this technology that Kaiser, responsible for its own reimbursement, is willing to move ahead after careful consideration of clinical benefits weighed against additional costs. Kaiser's actions should certainly cause other laboratories to reconsider their position on automated screening versus manual screening. **TDR**

(For further information, contact Gene Pawlick, M.D. at 510-559-5372.)

What Makes The AutoPap Instrument Tick?

ONE CRITICAL COMPONENT to the AutoPap instrument is its software algorithms.

"Mathematical morphology" is the design philosophy. This deals with the dynamics of shapes. It is a branch of mathematics which allows shapes to be divided by shapes. (Think of a wine glass divided by a kitchen plate.) It is a segment of mathematics which is non-commutative, non-additive, non-linear and difficult to comprehend.

AutoPap uses mathematical morphological algorithms to analyze normal versus abnormal cell structure. It produces no "graphic" in the true sense. Rather, it produces measurements of what is in the image. It is these measurements that provide the basis for future data set comparisons with other clinical information.

Processing speed is another strength of AutoPap. The average mammogram contains seven megabytes of data. The average Pap smear contains *four gigabytes* of data!

In seven minutes, AutoPap can analyze one Pap smear. It requires a computation rate of 15 billion instructions per second (BIPS). Compare this with a desktop computer, which operates in millions of instructions per second (MIPS).

Fifteen Morpho computers (each with ten chips) come packed inside every AutoPap instrument. Each Morpho computer handles 1 billion instructions per second. That's how AutoPap gets enough crunch-power to speedily process a single Pap smear!

Automated Cytology Update

SBCL Makes System-Wide Commitment To AutoPap

Hands-on use of new Pap technology provides strong evidence of improved screening outcomes

SOMEONE ALWAYS HAS TO BE FIRST to adopt new technology. In the case of automated cytology, it will be **SmithKline Beecham Clinical Laboratories** (SBCL).

SBCL and **NeoPath, Inc.** announced a four-year national agreement between the two companies on October 9 which will eventually allow SBCL to process 100% of its annual Pap smear volume using NeoPath's AutoPap® Primary Screening System.

SBCL screens more than 5.5 million Pap smears annually, so this is a major development in the field of cytology. Among the three blood brothers, it places SBCL in the forefront and represents a bold management decision to be the "early adopter" for this technology.

Right Course Of Action

Clients of THE DARK REPORT are the first to get inside knowledge about why SBCL considered this to be the right course of action. In a candid interview, Edward A. Kaufman, M.D., Vice President and National Medical Director for **SmithKline Beecham Healthcare Services** discussed some of the science and operational considerations which led to its contract with NeoPath.

"Our clinical experience with NeoPath started when we acquired their AutoPap QC system back in 1995," stated Dr. Kaufman. "Once installed in our designated laboratories, the system proved the concept by improving our rate of detection.

"To be specific, this system allowed us to detect five times more false negative low grade lesions or worse," he said. "We detected eight times more false negative high grade lesions or worse. These numbers were a strong validation of the potential for automation to improve a manual process."

Working With The System

"Once the AutoPap Primary Screener was available, we began working with that system," continued Dr. Kaufman. "Set to screen at 50% 'no review,' the system performed as well as humans. Set to screen at 25% 'no review' [the level approved by the FDA for primary screening], the AutoPap System was definitively better than humans.

"This hands-on experience was critical to our belief that the AutoPap Primary Screening System could deliver both clinical and operational benefits in a high-volume commercial cytology laboratory," he added. "Another key influence was the **Blue Cross/Blue Shield** study. Released earlier this year, it evaluated the cost-effectiveness of several automated cytology technologies. It gave the AutoPap Primary Screening System a favorable evaluation.

"In using the AutoPap technology, we saw improved sensitivity and specificity," Dr. Kaufman observed. "There were fewer false negatives and there were fewer false positives. Within our cytology labs, the number of slides referred to pathologists for review declined. The consequences of improving the screening step ripple through the entire laboratory and give the clinician and his patient a more accurate Pap smear diagnosis."

Because the AutoPap Primary Screening System is interactive with cytotechs, their response and input was a factor in SBCL's decision. "Initially there was some apprehension by cytotechs when these instruments first appeared in their laboratories," recalled Dr. Kaufman. "But as cytotechs began working with these instruments, three interesting things resulted."

Cytotechs More Involved

"First, many cytotechs become more involved in the screening process," he continued. "It captured their attention and caused them to rethink the science behind the Pap smear. Second, they became intrigued by what AutoPap does and how it applies innovative technology to screen a Pap smear.

"Third, a significant number of cytotechs liked the way the instrument was "teaching" them. When the cytotechs get the 75% of the slides requiring manual review, they also get AutoPap's ranking in order of possible abnormality. The objectivity of this feedback loop appealed to many cytotechs."

From an operational standpoint, SBCL expects modest benefits from the current generation of AutoPap technology. "We don't see a big impact in turnaround time, for example," responded Dr. Kaufman. "For the 25% of the results which are 'no review,' they can be reported within 24 hours. The other 75% of the slides still undergo a manual review."

Handle More Pap Smears

"It does give us additional capacity for handling more Pap smears," he noted. "This is important in localities where there is an absolute shortage of trained cytotechs. It is also important for us where we gain additional business, such as from our new contract with **Aetna/U.S. Healthcare**. The AutoPap

The 25% Factor: More Lab Capacity

As a primary screener, AutoPap can process and classify 25% of the Pap smears as normal and requiring no manual review. The remaining 75% of the slides undergo manual review.

This can permit the laboratory to increase capacity, as the example below demonstrates. If a laboratory can process 100,000 slides per year manually, then introducing the AutoPap with its 25% "no review" capability allows the same lab to process 133,333 slides, with no changes to the composition or number of cytotechs.

How The 25% Factor Expands Capacity...

	Conventional Lab	AutoPap PS Lab With Reduction In Cytotechs	AutoPap PS Lab With Increased Pap tests
Annual Tests Performed	100,000	100,000	133,333
AutoPap "No Review" Slides (25%)	0	(25,000)	33,333
Required Tests For Cytotech Review (75%)	100,000	75,000	100,000

instruments free up our cytotechs to handle the new volumes of testing from such contracts."

In developing national contracts with large HMOs, SBCL has emphasized its system-wide information system capability. The potential of AutoPap to feed data into that information system appealed to SBCL.

Capturing Data

"We recognize that AutoPap can capture data in a useful way," said Dr. Kaufman. "We would like to eventually retrieve that data and compare the Pap smear findings with biopsies and subsequent Pap smears for individual patients. We believe that matching these data sets can generate additional knowledge about how to diagnose and treat particular patients. For example, can it help us identify which cervical dysplasias will develop into real disease, namely cervical carcinomas, and which will not?

"These opportunities do not exist today, because manual screening procedures cannot capture quantitative cytological information the way AutoPap does," added Dr. Kaufman. "We anticipate that linking these algorithms with other data sets will allow us to identify useful relationships."

Reimbursement An Issue

As with any new healthcare technology, reimbursement is an issue. SBCL believes that payers will respond favorably to the clinical performance of AutoPap as a primary screener. "Most managed care organizations (MCO) are just beginning to evaluate automated cytology," observed Dr. Kaufman. "It will take time for the HMOs to gain experience with all aspects of automated cytology technology.

"From a strategic perspective, we think that the demonstrated gains in sensitivity and specificity for automated Pap smear screening will be recognized," he said. "Improvements in the rates for false positives and false negatives create a variety of benefits for patients, clinicians, and the payers.

"At SBCL, our message will be one of accuracy. We think consumers, physicians and the healthcare community will respond to that message. It is a better Pap smear.

"Whether automated cytology screening for Pap smears becomes the standard of care is something which will be determined by clinicians, professional associations, government healthcare agencies, and similar experts," continued Dr. Kaufman. "Because this technology is still new and unfamiliar, it will take a while for the clinical community to understand the impact it can have for improving healthcare outcomes."

Committed To Technology

Overall, Dr. Kaufman was clear about SBCL's evaluation of the AutoPap Primary Screening System. "This is a technology to which SBCL is committed," he said. "In hands-on usage, this instrument has demonstrated compelling reasons for our company to move ahead and introduce this technology throughout our system.

"We are confident that its potential to improve the screening and diagnosis of Pap smears will be recognized by all segments of the healthcare community," concluded Dr. Kaufman.

For pathologists and clinical laboratory executives, the move by SBCL to acquire and incorporate this technology should not be underestimated. On one hand, it is a sign that this technology is maturing. On the other hand, it is evidence that the marketplace is ready to raise the standards for what type of Pap smear processing represents highest quality for the patient. **TDR**

(For further information, contact Tom Johnson at SBCL: 610-454-6202.)

PathSOURCE Is Newest Pathology Consolidator

Company's strategy is to use regional hubs to preserve pathologist practice autonomy

CEO SUMMARY: Based in New York, PathSOURCE becomes the newest pathology network and services company to hit the market. PathSOURCE's organizers want to link "best in class" dermatopathologists and academic pathology subspecialists to compete for outreach pathology specimens. PathSOURCE is further marketplace evidence that pathologists must innovate or find themselves underutilized.

WITH THE GOAL OF CONTROLLING their own destiny, a group of academic-oriented pathologists recently formed their own pathology network and services company.

Called **PathSOURCE, Inc.**, the company will compete for pathology specimens by creating regional pathology hubs. Each hub is to be developed using a combination of pathology practice acquisitions, strategic alliances, and networks incorporating existing pathology practices. The company is based in Port Chester, New York.

Doctor-Directed Company

"Our business objectives are simple," stated Robert J. Friedman, M.D., Chairman and CEO of PathSOURCE. "We want to operate a doctor-directed company which uses regionally-based pathologists to provide a 'best medicine' level of dermatopathology and anatomic pathology services.

"We believe that anatomic pathology can play an important role in the healthcare world of the future," continued Dr. Friedman. "But unless pathologists change the way they deliver pathology services, many will find themselves shut off from the specimens they need to practice their profession."

Two pathology practices formed PathSOURCE. **Dermpath, Inc.** of Port Chester, New York and the **Institute for Dermatopathology** in Philadelphia, Pennsylvania developed the idea and incorporated the company.

PathSource's founding pathologists have an interesting resource aiding them in this business venture. "Dan Lufkin, a co-founder of **Donaldson, Lufkin & Jenrette** (DLJ), serves on our board of Directors," noted Dr. Friedman. "He is currently a principal of **Questor Partners Fund**. Questor made a $25 million equity investment in PathSOURCE.

"Lufkin has personal experience with dermatopathology," commented Dr. Friedman. "As various pathology PPMs approached us with acquisition offers, my colleagues and I would ask his advice. You could say that he became an informal mentor, guiding us through the process of evaluating the acquisition offers and business strategies of these various pathology PPMs.

"Like many other pathologists, we did not like the idea of being bought out

by business people who weren't physicians," recalled Dr. Friedman. "Working as an employee was not an attractive option. Giving up our autonomy as doctors was equally unacceptable."

Academic Pathologists

"It took about two years for all these events to transpire. During this time, Dan Lufkin became increasingly interested in the business potential of a pathology network and services company," he continued. "For our part, we noticed that many academic pathologists were beginning to realize that their services were increasingly underutilized.

"The reasons are obvious," observed Dr. Friedman. "Academic programs are getting cut back. Managed care is taking reimbursement away from academic and teaching centers. In the outreach market, managed care companies want to limit pathology providers to a select panel. This denies academic and non-provider pathologists access to AP specimens."

PathSOURCE co-founder Richard Jacoby, M.D. added another important point. "As managed care grows, the accession curve for inpatient AP specimens declines. Plus, AP specimens are transportable. The vast majority of AP specimens in the United States could be done in regional centers."

Experience With Dermpath

"This is a threat to local pathologists," observed Dr. Jacoby. "We recognized that if we did not respond to these market trends, we would lose access to specimens and control over the way we practice medicine and relate to clinicians and patients.

"The pathologists who organized PathSOURCE realized that businessmen were going to control medicine," he continued. "Any pathologist who doubts this fact need only look at the representatives sent by pathology PPMs to discuss acquiring their practice. Seldom is it a doctor, and seldom do doctors play the major role in the boards and executive management of the pathology PPM."

"That is why, during this two-year period of evaluating the various PPM opportunities which were shown us, we decided to create a doctor-driven pathology network company," he added.

"Our goals are basic. First, we want PathSOURCE to be outpatient-focused. Dermatopathology is our specialty and we understand that market," said Dr. Friedman. "We want to develop as a regional resource. This will be accomplished by creating strategic alliances with the anatomic pathology departments of recognized academic sources.

> ***"As pathologists, we want PathSOURCE to be a brand name to doctors, patients, employers and MCOs. Branding takes, first and foremost, a quality product, then time, money, and people who know how to build a brand."***
>
> ***Robert Friedman, M.D.***
> *Chairman & CEO, PathSOURCE, Inc.*

"This alliance of dermpath and AP in a regional setting is the platform which allows us to pursue managed care contracts," he noted. "Our initial efforts will be to establish regional organizations along the Northeast corridor."

According to Dr. Friedman, serious negotiations are under way with a number of pathology practices who are interested in affiliating with PathSOURCE. "Because our emphasis is on quality clinical services, we will only add about four to five partner practices per year," he concluded. "We want PathSOURCE to be the highest quality diagnostic pathology in the marketplace." TDR

(For further information, contact Robert Friedman, M.D. at 877-728-4768; Richard Jacoby, M.D. at 800-257-0117.)

Lab Specialists Acquired By Kroll-O'Gara Company

Fast-growing toxicology laboratory decides to become part of a security services firm

CEO SUMMARY: Laboratory Specialists of America has demonstrated a multi-year capability to increase revenues and boost earnings. The merger with Kroll-O'Gara provides it with ample capital to intensify its own acquisition program. One key to Laboratory Specialists' success is its recognition that it is in a service industry, not a test results industry. Client service is a hallmark of this progressive laboratory company.

WHEN A MUTUAL FUND MANAGER bought stock in both **Laboratory Specialists of America** and **Kroll-O'Gara Company**, the last thing on his mind was a merger of the two firms.

Yet that is eventually what happened after he encouraged executives from the two companies to meet. On October 22, Kroll-O'Gara announced its purchase of Lab Specialists for $29 million in stock, with the deal set to close in December.

"We met Kroll-O'Gara through a mutual fund manager who invested in companies specializing in corporate security services," said John Simonelli, Chief Executive Officer at Lab Specialists. "He recognized that both companies had complementary strengths. He encouraged us to meet with Kroll-O'Gara."

Laboratory Specialists of America is a drugs of abuse testing laboratory which has tripled its annual revenues during the last three years, from $5 million to $15 million per year. *(See TDR, December 4. 1995.)*

Kroll-O'Gara Company is a $190 million firm offering corporate and private security services, including internal and external fraud prevention. Kroll-O'Gara finds drugs of abuse testing to be a perfect complement to its full menu of corporate security services.

"There are two primary reasons why we agreed to sell to Kroll-O'Gara," stated Simonelli. "First, they provide us with ample funds to acquire more tox testing business. Even though our earnings were growing 50% per year, our stock price traded at a relatively low multiple, making it more difficult for us to finance acquisitions."

Cross-Sell Clients

"Second, it improves our ability to boost sales by giving us access to Fortune 500 clients and allowing us to cross-sell existing clients of Kroll-O'Gara," he continued. "Our shareholders benefit from this merger as well, because of the value which Kroll-O'Gara paid for our lab."

According to Simonelli, Kroll-O'Gara intends to allow Lab Specialists to continue its growth strategy. "We will operate without any fundamental

changes to our existing organization," he explained. "They want us to continue with acquisitions. In fact, many laboratories now in discussions with us about selling their drugs of abuse testing operations are excited about the merger. They recognize the increased financial strength behind us. That is why we believe our acquisitions program will actually move faster."

Laboratory Specialists of America is a successful business model that has much to teach the clinical laboratory industry. Both Simonelli and his partner, Larry Howell (President of Lab Specialists), come from a corporate management background, not healthcare. Their ability to generate sustained growth and increased profits during the 1995-1998 period demonstrates that professional management techniques have application in managing laboratories.

Key To Success

One key to their success is customer service. "We emphasize customer service," stated Simonelli. "After buying a book of business, we work hard during the transition period. We spend a lot of time understanding our new clients. For us, lab testing is not about low cost, it is about anticipating and meeting the needs of our clients.

"If we do a good job with service, our clients reward us with loyalty. 'Lowest price' ceases to be the primary reason they chose our lab over competitors," he continued. "That is why we provide the personal touch with every client. It sets us apart from the competition.

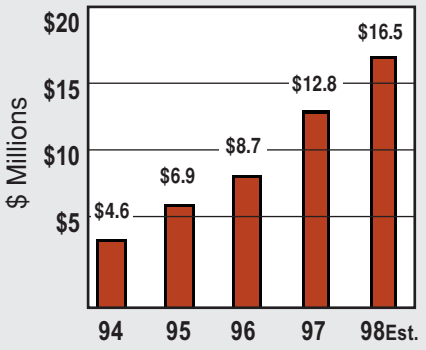
"Another element in our success is that we solve problems immediately and permanently," added Simonelli. "This is a service industry, not a test results industry. We appreciate the difference. If our client has a problem, we want to fix it immediately. We also want to fix the system that created the problem so it won't happen again.

Laboratory Specialists Of America

At-A-Glance

Headquarters: Oklahoma City
Main Lab: New Orleans
1997 Employees: 111
Chair & CEO: John Simonelli
President & COO: Larry Howell
Service Area: Sunbelt States
(with collection sites and logistics nationally)

Five Year Revenues



"I would say that many laboratories will fix a customer's problem, but do not solve the ongoing issues which generate similar problems over and over again. That frustrates clients. It is why we place a high priority on responding to the customer's needs, then permanently fix our system to prevent it from triggering the same problem again in the future."

Independent clinical laboratories can expect to see more of Laboratory Specialists in the future. "We continue to be interested in acquiring the drugs of abuse testing business from regional laboratories looking to exit that segment of the business. We are involved in those kinds of discussions every day." TDR

(For further information, contact John Simonelli at 405-232-9800.)

Bankruptcy Court Okays Unilab's Offer For Meris

Financial pressure and market competition force another California laboratory to close

CEO SUMMARY: Meris Laboratories, Inc. is now history. California's intense competitive market pushed the company into bankruptcy and eventual sale to Unilab, Inc. Even as Unilab moves to consolidate and integrate Meris' clients and operations into its system, attention is focusing on BioCypher Laboratories. Observers believe this troubled laboratory may be next on the chopping block.

ONCE THE BANKRUPTCY COURT approved **Unilab, Inc.'s** bid to purchase **Meris Laboratories, Inc.**, it took little more than a week to consummate the sale.

As of last Friday, November 6, Unilab was the new owner of Meris Laboratories. "The transaction was closed on Thursday," stated Philip Tremonti, President and CEO of Meris. "We handed the keys to Unilab on Friday morning. They now own Meris lock, stock, and barrel."

Unilab was the only company to place a bid to purchase Meris with the bankruptcy court. **Laboratory Corporation of America** and **SmithKline Beecham Clinical Laboratories,** each with a significant presence in California, declined the opportunity to bid for Meris.

Only One Bidder

"With no other bidders, the bankruptcy judge approved our purchase of Meris," said Richard Michaelson, a Unilab Director and former CFO. "Because of Unilab's familiarity with Meris and the primary market areas it serves, we intend to move expeditiously to integrate their operations with ours."

Annual revenues at Meris are about $28 million, compared to Unilab's $216 million. After integration, Unilab will approach $250 million in revenues, all of it originating in California.

"No Cash" Transaction

Unilab acquired Meris in a "no cash" transaction for $16.52 million in notes, payable over an eight-year period. *(See TDR, September 28, 1998).* According to Michaelson, the price was based on Meris' EBIDTA (earnings before interest, depreciation, taxes and amortization). Financial analysts consider EBIDTA to be a more relevant benchmark for determining the market value of a company.

"We think the price paid for Meris fairly reflects its value to us in today's marketplace," noted Michaelson. "One can certainly make the presumption that other laboratories, comparing Meris' assets against their own laboratory infrastructure, decided it was not in their interest to enter a higher bid."

Unilab, the largest commercial laboratory operator in California, pursued the Meris acquisi-

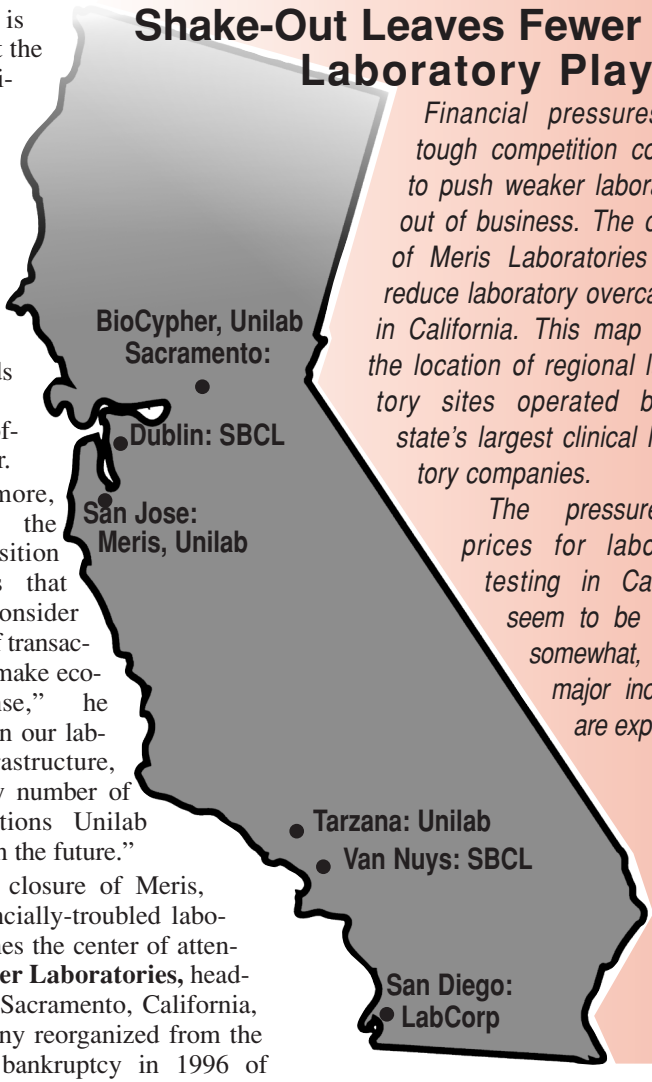
tion as a good match to its existing operational structure. "Unilab is thrilled about the Meris acquisition," commented Michaelson. "We believe that cost efficiencies in our organization make it possible to do these kinds of acquisitions in a profitable manner.

"Furthermore, we believe the Meris acquisition demonstrates that we will consider these types of transactions if they make economic sense," he added. "Given our laboratory infrastructure, there are any number of business options Unilab can explore in the future."

California's Commercial Lab Shake-Out Leaves Fewer Big Laboratory Players

Financial pressures and tough competition continue to push weaker laboratories out of business. The closure of Meris Laboratories helps reduce laboratory overcapacity in California. This map shows the location of regional laboratory sites operated by the state's largest clinical laboratory companies.

The pressure on prices for laboratory testing in California seem to be easing somewhat, but no major increases are expected.



With the closure of Meris, another financially-troubled laboratory becomes the center of attention. **BioCyper Laboratories,** headquartered in Sacramento, California, is the company reorganized from the Chapter 11 bankruptcy in 1996 of **Physicians Clinical Laboratories** (PCL).

BioCypher's financial travails have spawned a cascade of rumors and stories. It is known that a significant number of BioCypher's executives and middle managers terminated their employment in recent months.

Further, negative cash flows at BioCypher caused it to borrow money on more than one occasion during the last 18 months. *(See TDR, September 28, 1998.)* Apparently a major cause for the negative cash flow are problems in billing and information systems.

Ex-employees have said that as many as one in three requisitions cannot be billed, for various reasons. One unconfirmed story in circulation says that BioCypher has as many as 130,000 test requisitions in suspense.

Despite its financial problems,

BioCypher still handles a specimen volume worth $50 million to $60 million per year. This means BioCypher is still a significant laboratory competitor in the marketplace. Should BioCypher fail to resolve its financial problems, it may be forced to enter bankruptcy for the second time in two years. *(See TDR, November 25, 1996.)*

Were BioCypher to enter bankruptcy, it is not certain how a second bankruptcy would be be resolved. Would a rescuer be willing to invest more money and management resources toward restoring BioCypher to fiscal health as an independent company? Given California's punishing market for lab services and BioCypher's deteriorating condition, it would seem unlikely that another White Knight would appear.

It is more likely that the bones of the former PCL would be picked over by competing laboratories in California. Since BioCypher would be a crippled organization, only commercial labs with a lot of expertise and turnaround resources are logical bidders to buy whatever is left of BioCypher in such a bankruptcy action.

Claims Another Victim

It will take several more months before the fate of BioCyper is known. In the meantime, the demise of Meris Laboratories means that California's intensely competitive managed care marketplace has claimed another victim.

The dismantling of Meris' central laboratory further reduces overcapacity in the state and comes on the heels of the various Chapter 11 and Chapter 7 bankruptcies by clinical laboratories in California during the past three years. Each laboratory closure is a direct result of the fact that managed care refuses to subsidize unused laboratory capacity.

As the overcapacity of laboratory testing is whittled down through bankruptcies, downsizing, and reengineering, it is uncertain whether the current "supply" of laboratory testing capacity is reaching equilibrium with the existing volume of laboratory specimens.

Until supply (capacity to provide testing) reaches a balance with demand (the volume of lab specimens), price levels for lab tests in California will remain at rock bottom levels. Any commercial laboratory with excess capacity has an incentive to bid for additional work using a marginal cost pricing strategy.

Point Of Equilibrium

It is the belief of THE DARK REPORT that such a point of equilibrium may soon be reached in California. BioCypher's laboratory operations represent a considerable amount of laboratory capacity. Common sense economics says that no investor will chose to sink additional capital in the company to keep it afloat.

During the last three years, laboratory operations at all the major commercial labs have undergone continual downsizing and reengineering. As a result of these efforts, not much "fat" remains to be squeezed from the California operations of Unilab, SBCL, and LabCorp. On the plus side, these activities have helped improve the financial situation at these labs.

Add these facts up and it is reasonable to conclude that, during 1999, competitive dynamics for laboratory testing in California will enter a new market phase.

However, these developments in the clinical laboratory marketplace will play out in a managed care environment where the HMOs are undergoing their own financial problems. Even if clinical laboratories find the resolve to hold out for improved reimbursement and better pricing, California-based HMOs may not have the cash flow to accomodate such increases to the cost of laboratory testing. **TDR**

(For further information, contact Philip Tremonti at 408-452-3100 and Richard Michaelson at 201-525-1000.)

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

HBO & Co. is the latest to fall victim to consolidation mania. **McKesson, Inc.** is purchasing HBO for $14 billion in stock. McKesson wants to complement its services as a pharmacy benefits manager with HBO's extensive health information system capabilities. Combined, the two companies will have more than $21.0 billion in annual revenue

MORE ON:...HBO & CO. News of the acquisition was welcomed by **Columbia/HCA** VP James Fitzgerald. "This can't be anything but very positive," he said, adding that he hoped McKesson would use HBO's expertise to create integrated information products for monitoring drug inventories, patient-information databases, and accounting systems. McKesson already has a five-year, $5 billion contract with Columbia. Could this be a wedge in the door for HBO to pitch its information system products to Columbia? **Meditech** has had an exclusive lock on Columbia's IS business for several years.

Healthworks Alliance, based in King of Prussia, Pennsylvania, continues to push its products into the marketplace. The company recently was awarded a contract by **Tenet Healthcare Corporation** to provide its Compliance Checker™ software product in all 120 of Tenet's acute care hospitals. It is a major vote of confidence for Healthworks' product and demonstrates how laboratory compliance is becoming a major management issue.

JVHL LAB NETWORK INKS NEW PROVIDER AGREEMENT

Joint Venture Hospital Laboratory Network (JVHL), the 25-hospital lab consortium in Greater Detroit, announced an agreement to provide laboratory services for **Universal Standard Healthcare**, a major third party administrator in Detroit. JVHL currently has contracts to provide services to more than 1.1 million enrollees, a feat unmatched by any other regional laboratory network in the United States

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THE DARK REPORT has preached it for years. Now Alan Greenspan, Chairman of the **Federal Reserve**, confirms that new management techniques make the difference in a company's success, He recently observed that corporate managers are making more efficient use of capital by using new management practices to redesign their businesses. "Total quality management, customer satisfaction... we've got a whole generation of executives who are thinking differently," says Federal Reserve Vice Chair Alice M. Rivlin, who agrees with Greenspan on this point. Question is: how many lab administrators are learning and applying these new management techniques to keep their laboratories competitive?

Beckman-Coulter Corporation announced on October 19 that further staffing cuts would be made during 1999. Since Beckman acquired Coulter a year ago, it has reduced its work force by 8%, or 980 full- and part-time positions. Beckman's earnings are lagging behind analysts' expectations. Savings from integrating the two companies have not yet offset lower revenues from falling diagnostics sales and negative foreign exchange effects.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, November 30, 1998

THE DARK REPORT

UPCOMING...

- *Three Blood Brothers' Third Quarter Earnings Reveal Current Market Conditions.*
- *Total Laboratory Automation Update: Who's Moving Ahead And Why.*
- *East Coast Laboratory Uses Strategic Planning To Fuel Explosive Growth In Profits.*
- *News From The Dark Report's Upcoming Private Pathology Income Symposium.*