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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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Applying Heat to the Pressure Cooker

I AM STRUCK BY THE NON-STOP TIDAL WAVE OF CHANGE which continues to strike at clinical laboratories and pathology practices. Although it may be tough to quantify the volume of change, that task becomes easier if you use each issue of THE DARK REPORT as a measuring post of change.

Take this issue, for example. As we go to press, **Quest Diagnostics Incorporated's** acquisition of **SmithKline Beecham Clinical Laboratories** (SBCL) remains undone. Should it happen, virtually every laboratory in the United States will be touched by the consequences, in one fashion or another. If the acquisition never happens, a different SBCL will return to the marketplace, with a different set of consequences to the lab marketplace.

Another significant change is the wedding of **AutoCyte, Inc.** and **Neopath, Inc.**, scheduled to close later this year. *(See pages 9-16.)* The two companies, along with **Cytyc Corporation**, have already changed the way the economics of cytology and Pap smear screening is viewed by laboratorians. That alone will trigger a cascade of different responses by laboratories in coming years to further advances in cytology technology.

Then there is **Associated Pathologists Laboratories** (APL) of Las Vegas. Again THE DARK REPORT identifies a success story where proactive lab management, combined with an investment in sales and marketing, is paying big dividends for an independent commercial laboratory. *(See pages 6-8.)* As you read about APL's efforts to refine a hair-based drug screening test, consider how this new technology, and this new approach to drug screening, might alter the drugs of abuse testing marketplace during the next few years. I'll bet the APL owners are glad they have a solid patent position backing their hair-based drug test.

Another valuable intelligence item provided in this issue is our editor's introduction to the recent merger of **Healtheon Corporation** and **WebMD, Inc.** *(Page 17.)* Talk about the potential for change! If this company can halfway succeed in its goal of using the Internet as the "copper wire" to transmit healthcare information and transactions between providers, then we will all need to reinvent ourselves, including THE DARK REPORT, sooner rather than later! Maybe a good metaphor for this is that every change to our industry is like adding heat to a pressure cooker. As managers, we must figure out a way to release the pressure. Otherwise, like an overheated pressure cooker, our respective lab organizations may explode from unreleased pressure. TDR

Quest Holds Off on SBCL, Leaves the Door Open

Disagreement over SB's terms of access, price for future Quest lab data is hold-up

CEO SUMMARY: It's a cryptic situation as of press time. Quest Diagnostics issued a public statement on July 1 stating that its acquisition of SmithKline Beecham Clinical Laboratories would not close on July 2, as expected. Since that date, there's been no further comment on the situation. Wall Street analysts and Quest competitors are watching daily to see whether or not this merger is finalized.

IT WAS JULY 1 WHEN **Quest Diagnostics Incorporated** issued an unexpected public statement concerning its acquisition of **SmithKline Beecham Clinical Laboratories** (SBCL).

It was a statement that the acquisition of SBCL "would not close on July 2, as previously indicated." As of press time, Quest Diagnostics has made no further public statement about the acquisition and its status. As part of this announcement, the laboratory company also declared that it would not close the $300 million financing package which was scheduled to fund on July 2.

In Quest's second quarter earnings release last Friday, the only reference to the SBCL acquisition was a comment by Quest Chairman and CEO Kenneth W. Freeman that he remains "hopeful that we will resolve the remaining issues and complete the transaction."

The point of dispute between **SmithKline Beecham PLC** (SB) and Quest Diagnostics apparently involves an ancillary contract to the purchase agreement. This agreement gives SB non-exclusive access to Quest Diagnostic's proprietary clinical laboratory database, for an unspecified amount of money.

As THE DARK REPORT has noted, clinical laboratory information will be the true added-value product for clinical laboratories in the future. The lack of agreement between SB and Quest Diagnostics thus involves a major issue, since both companies appreciate how valuable that information will be in coming years.

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

R. Lewis Dark, Founder & Publisher. 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).

That the two companies would get into a serious squabble about access and payment terms for future lab data provides an interesting validation of THE DARK REPORT'S predictions that laboratory data is the gold mine for future income and profits. Because SB and Quest have not agreed on terms and price for SB's access to this data, a transaction valued at almost $1.4 billion and involving 25,000 employees is in limbo.

No Comment On Negotiations

Officials at Quest Diagnostics tell THE DARK REPORT that they cannot comment on the status of negotiations. Nor will they speculate on whether the acquisition will ever take place. Among Wall Street analysts following this situation, there are many rumors, but little certainty that rumors have truth.

One individual who understands the dilemma facing Quest Diagnostics and SB believes there *is* a major point of dispute on this issue. "Proprietary laboratory data, particularly as it relates to clinical trials, has great value to Quest," said Joe Plandowski, President of **The Lakewood Consulting Group** in Lake Forest, Illinois. "It also has value to SmithKline. Therein lies the rub."

Potential Business Problem

"In coming years, Quest Diagnostics wants to provide clinical trials and laboratory testing for any pharmaceutical company while maintaining total confidentiality for each drug company client," continued Plandowski. "Yet, if those drug companies perceive that SmithKline might access that data, it creates a business problem for Quest."

Plandowski speaks from personal experience on this issue. While an executive with SBCL during the 1980s, Plandowski was involved in clinical trials done by SBCL for **Eli Lilly & Co.** "Eli Lilly was very concerned about the ties between SBCL and SmithKline," recalled Plandowski.

"This was in the mid-1980s. Relations between Lilly and SB were strained. Lilly eventually helped start another clinical trials company to handle its testing," he recalled. "So I have seen, first-hand, how tricky it is for a lab connected to SB to do clinical trials work for another pharmaceutical competitor.

"Thus, I believe that there is genuine concern at Quest Diagnostics on how to handle the way SB can access its lab database," mused Plandowski. "There is also another aspect to why this particular issue may be a deal-stopper so late in the acquisition process.

"That involves the CEO of SmithKline Beecham, Jan Leschly. In recent years he has demonstrated a willingness to take his toys and go home if he can't get what he wants," observed Plandowski. "Just in the last 18 months, separate merger deals with SB and **American Home Products** and SB and **Glaxo Wellcome** were dissolved at Leschly's initiative.

"The press was full of comments about Leschly's insistence that certain aspects of the merger be done to his liking or else," added Plandowski. "There are certainly similar aspects of that in the Quest-SBCL deal, particularly coming the day before the scheduled closing."

Plandowski's two points certainly fit the facts as they can be ascertained at this time. But his final comment may yet prove the most prophetic. "I have negotiated many laboratory sales transactions. These kinds of problems, so late in the game, make it tough, both professionally and emotionally, for both parties to go through with the sale. No one should be surprised if this acquisition is now unraveling and never takes place!" TDR

For further information, contact Joseph Plandowski at 847-295-8805.

Lab Industry Briefs

SCANDAL AT HBO & CO. TAINTS MCKESSON HBOC

FIVE EXECUTIVES WERE SACKED by **McKesson HBOC Inc.'s** Board of Directors last month in response to allegations of financial improprieties.

All five were employed by HBOC prior to its acquisition by McKesson last year. The terminations were accompanied by the resignation of McKesson's CEO, Mark Pulido, and CFO, Richard Hawkins. Both men had supervised McKesson's acquisition of HBOC.

Auditors and investigators, working since last April, found evidence of such financial shenanigans as backdating signed contracts into the previous quarter. This would allow HBOC to manage its financial statements in such a way as to meet investor targets, even though these sales were not final.

McKesson HBOC announced that earnings for three prior years will be restated as a result of its internal investigation. Revenue will be reduced by $327.4 million and net income from continuing operations will be reduced by $791.5 million.

HBOC is familiar to many laboratory executives for its purchase of **Advanced Laboratory Group** (ALG) in the mid-1990s. ALG had developed a successful laboratory information system (LIS) software package before it was gobbled up by HBOC.

HBOC fueled its rapid growth by a series of acquisitions, complemented by an aggressive sales and marketing effort. It was a high-flying stock and many analysts praised McKesson for acquiring HBOC.

Fired executives were Albert Bergonzi, who had been the pre-merger President and CEO of HBO; David Held, who was HBO's pre-merger CFO and Controller; Jay Lapine, HBO's pre-merger General Counsel; and Michael Smeraski, who led HBO's sales of systems that automated functions across various healthcare organizations. Former HBO CEO Charles McCall was ousted as McKesson HBOC's Chairman and dismissed as an employee.

Expect more repercussions as the full scope of the alleged financial mismanagement is made public. These events will certainly distract HBOC from its core software business.

PATHOLOGY ASSOCIATES MEDICAL LABS PURCHASES TREASURE VALLEY LABS

INDEPENDENT commercial laboratories continue to thrive by concentrating on their immediate service regions.

One example is **Pathology Associates Medical Laboratories, Inc.** (PAML) of Spokane, Washington. It is a major participant in **PacLab Network Laboratories** in Washington, a flourishing statewide regional laboratory network. *(See TDR, October 19, 1998 and November 30, 1998.)*

Now PAML is building a service base in Boise, Idaho by acquiring **Treasure Valley Medical Laboratories, Inc.** (TVL), located in Boise. Partner in the acquisition is **Saint Alphonsus Regional Medical Center**, also located in Boise.

The goal is to combine testing from St. Alphonsus and TVL in Boise to increase the test menu performed locally while gaining economies of scale. This should give PAML a service boost in Western Idaho.

With the Boise acquisition, PAML now has a string of satellite laboratories in Eastern Washington and

Western Idaho which make it the regional laboratory of choice in what is primarily a rural area.

TVL has been the acquisition target of many would-be buyers. Its President, Skip Pierce, built TVL into the dominant commercial laboratory player in Western Idaho.

"SCRUPULOUS" CODING BY HOSPITALS CAUSES LOWER MEDICARE BILLS

THINK THE FEDERAL GOVERNMENT'S Medicare fraud and abuse crackdown is having little impact? Think again.

Recent convictions in federal court of two mid-level executives of **Columbia/HCA Healthcare Corp.** for defrauding government insurance programs is just one more important milestone in the Fed's anti-fraud campaign.

Laboratory executives already know the full force and power of government fraud investigators. Commercial and hospital laboratories forked over close to $1 billion in settlements with the OIG during the 1990s. The entire lab industry is vigorously implementing compliance programs.

Now hospitals have got the message about fraud and abuse. Medicare spending rose at a record low of 1.5% last year, and spending actually dropped during the first six months of 1999! While this was occurring, the OIG reports that Medicare "only" lost $12.6 billion through improper billing in 1998, compared to $23 billion in 1997.

Here's the remarkable fact about a major change to hospital billing practices. For the first time since Medicare was launched in 1966, hospitals' billings for the year were, overall, for less serious illnesses than the previous year.

Medicare officials point out that this does not mean the over-65 population is getting healthier. Rather, they interpret this to mean that more hospitals are becoming "scrupulously accurate" in the diagnoses cited for medical claims.

In effect, hospital billing departments are coding conservatively. "People are definitely erring on the side of 'when in doubt, underbill it'," observed attorney Michael Jones of Boston-based **Choate, Hall & Stewart**. "That indicates almost a level of paranoia that some people have."

The Tampa convictions of mid-level hospital executives follow those of a recent Kansas City criminal case. In April, federal prosecutors won jury verdicts of guilty against two physicians and two hospital executives on criminal charges involving kickbacks for patient referrals. It shows that federal prosecutors are getting juries to understand complex healthcare laws and deliver guilty verdicts.

ABBOTT LABS DOES TWO ACQUISITIONS, REPORTS DIAGNOSTIC GAINS

SEEKING TO STRENGTHEN ITS PRODUCT LINES, **Abbott Laboratories Inc.** purchased two companies in recent months. Already the second largest diagnostics company in the world, Abbott needs size to remain competitive in the pharmaceuticals industry.

In June it purchased **ALZA Corp.**, a manufacturer of urology drugs and drug delivery systems. It followed that in July with the announcement that it would acquire **Perclose Inc.**, which manufactures medical devices.

Meanwhile, Abbott disclosed second quarter revenues and earnings, which increased 5.8% and 9.8%, respectively. The diagnostics division made a strong showing, increasing revenues by 8.22% over the same quarter last year. TDR

Assoc Path Labs Pursues Drugs of Abuse Testing

Proprietary hair testing capability supports rapid growth in this competitive testing niche

CEO SUMMARY: Since 1994, Las Vegas-based Associated Pathologists Laboratories has carved a thriving business from drugs of abuse testing. Its fast-growing toxicology business is built around a full-service menu of testing services. This includes a patented drug screen based upon testing hair samples, which can detect up to twice the number of drug users as the more common urine-based drug screen.

DESPITE THE FACT THAT drugs of abuse testing is a highly competitive, low margin business, **Associated Pathologists Laboratories, Inc.** of Las Vegas has developed a competitive advantage and is now reaping the rewards.

That competitive advantage is a patented hair test for drugs of abuse detection. Associated Pathologists Labs (APL) is successfully building its toxicology testing volume at annual rates which would be the envy of most labs.

"As most laboratorians know, drugs of abuse testing can be a lousy business," said Craig Shanklin, APL's Vice President, Marketing. "There is tremendous overcapacity among labs offering urine drug screening. That leads to price competition, and profit margins which can be razor-thin.

"Also, the recent explosion of on-site test kits is eroding what profitability remained for most traditional urine testing labs," he added.

Here is where the APL story takes an interesting twist. "Some years back, we did a strategic planning session," noted Shanklin. "We recognized the problems caused by overcapacity and poor profit margins. But we also realized that if we could distinguish ourselves from competitors, we would have a competitive advantage with an important benefit. We could charge higher fees if we offered something different than the competition."

Seeking Competitive Edge

"We began researching ways to improve the existing system of urine-based testing for drugs of abuse," he continued. "That is what originally led us to investigate using hair samples as a way to test for drugs of abuse."

It was 1994 when APL began offering drug screens based on hair samples since. Companies that screen employees for drug abuse find that the hair tests provide additional benefits over urine tests.

"To understand the advantages of hair samples over urine samples, it is necessary to look at what is happening in the workplace," Shanklin stated. "First, the positive rate for urine testing has declined steadily over the last six or seven years. We track this by following

SmithKline Beecham Clinical Laboratories' (SBCL) annual report on the average positive rates for drugs of abuse testing it performed during the year. We consider that to be a useful benchmark for national trends.

"Second, there is the adulteration problem with urine testing,"explained Shanklin. "In recent years, an entire industry sprang up to help drug users beat drug screens. Head shops and web sites sell a variety of products which are to be added to a urine specimen or ingested by the subject prior to providing a sample. Their objective is to create a negative result even though the subject has been using drugs."

Lab Industry's Response

"The lab industry's response to this trend was to test for adulterants, such as nitrites," said Shanklin. "Labs will report a negative test result, along with the detection of nitrites in the sample."

Executives at APL watched these trends develop. "That is why we looked for a way that we could differentiate ourselves from other labs offering drug testing, while providing a better solution to drug screening.

"Hair testing for drugs of abuse was our answer," declared Shanklin. "The benefits are clear and indisputable. One, unlike urine samples, hair samples cannot be adulterated. Two, hair samples can detect drug use going back as far as 90 days. Urine testing is generally only reliable for detecting drug use within the previous 72 hours."

Employer Can Collect

"Three, because the employer can elect to collect the hair sample themselves, it can lower the cost of the drug screen, since no outside collection service is involved," he said.

"Fourth, and more importantly, hair testing generates a higher number of positives," Shanklin said. "This is because of its 90-day lookback ability, its increased sensitivity, and its resistance to adulteration."

Shanklin's fourth benefit is the jackpot answer to the success of APL's hair testing program. Employers recognize that a hair test will detect more drug users among their employees than a urine test. But how many more?

"It is our experience that hair testing doubles the positive rate," answered Shanklin. "For employers, this is highly significant. It means hair testing allows them to identify drug users that would slip past a urine test.

"Since the goal of most private company drug testing programs is to identify any drug abuser prior to employment, this higher rate of detection is a valuable benefit," noted Shanklin. "It sets APL apart from competing labs that can only offer urine-based drug testing."

Tandem Gas Mass Spec

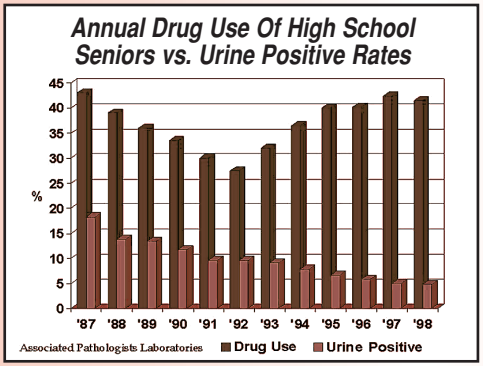
APL gives nothing away on turnaround time with hair testing. It reports negative results in 24 hours and confirms positive results within 72 hours. "We confirm all positives using a GC/MS/MS arrangement that operates in tandem. This permits us to have increased sensitivity with hair testing over urine testing."

As an independent regional laboratory serving Las Vegas and Nevada, APL's drug testing business has allowed it to create a national business. "Our largest customers are Fortune 1,000 companies," said Shanklin. "We operate a SAMHSA-certified laboratory and offer a full menu of drugs of abuse testing using both urine and hair samples."

This national business is large enough to support ten sales reps and four regional offices, in Chicago, Atlanta, Philadelphia, and Dallas. Growth has been steady, with hair testing leading the way. "Every year since 1995, we've seen more than double the

Drug Use increasing While Drug Screens Losing Their Ability to Detect Drug Usage

As drug users learn to beat urine-based drug screens, the positive rate declines even as drug use increases in America. Employers recognize the value of hair-based screens.



APL's Year-to-Year Growth
Urine versus Hair Testing

	Urine	Hair
1995	34%	12%
1996	8%	58%
1997	17%	42%
1998	15%	34%
1999E	24%	143%

On the left is a bar chart which shows the percentage rate of positive drug screens as reported by SmithKline Beecham Clinical Laboratories for the years indicated. It is graphed against drug use by high school seniors. It demonstrates that urine-based drug screens are not catching all drug users. At right is a table which shows the annual growth rate at Associated Pathologists Laboratories for its urine- and hair-based drug tests.

growth rate in the number of hair-based screens compared to urine-based drug screens," noted Shanklin. "Employers have significant interest in hair-based screens."

It's enough of a differentiation that **Laboratory Corporation of America** signed a referral agreement with APL. Anytime a LabCorp drug testing client would like hair testing performed, LabCorp refers the samples to APL.

APL has a few competitors in the hair sampling field. "Another established firm offers a hair-based drug screen," Shanklin said. "Their patents are based on RIA technology. In contrast, we use ELSIA technology, which we believe offers improved sensitivity and specificity."

APL's accomplishments in developing a patented hair-based drug screen, then successfully selling it to a national market, demonstrate that plenty of opportunities remain for clinical laboratories to make money. It requires some imagination, a sharp eye to spot market trends, and a willingness to invest money in developing a specialized service.

Success Not Happenstance

APL's success was not happenstance. Its leaders were bold enough to invest in research, then used professional sales and marketing to deliver their message to potential clients. With ten sales reps in the field, it is one reason why its scientific accomplishments are generating operating profits.

Associated Pathologists Laboratories' sustained profitability in recent years demonstrates that clinical laboratories can exploit a variety of niche testing opportunities as a way to diversify revenues and improve operating profits. **TDR**

For further information, contact Craig Shanklin at 702-733-7866.

Wedding Between AutoCyte and NeoPath Will Spawn A Single Prep/Screen System

AutoCyte

James B. Powell, M.D.
President & CEO

CEO SUMMARY: *Various technologies that automate cytology and Pap smear screening entered the clinical marketplace during the last four years. Because managed healthcare views new technology with a more skeptical eye than fee-for-service healthcare, THE DARK REPORT has provided extensive analysis for our clients on how and why the market has embraced or rejected this technology. It is our belief that automated cytology technology represents a good case study as to how other diagnostics technology, such as total laboratory automation, must deliver if it is to succeed in the clinical marketplace. With the impending merger of AutoCyte and NeoPath, the market acceptance cycle for automated cytology technology will enter a new phase. More importantly, new generations of these automated cytology systems will begin to find clinical application in areas beyond Pap smear screening, such as anatomic pathology. It is this fact which makes the AutoCyte/NeoPath merger a significant event. This exclusive newsmaker interview with the top executive officer for each company allows them to tell their story directly to our clients and readers.*

NEOPATH®

Alan C. Nelson, Ph.D.
Executive Chairman

NOTE: Separate interviews were conducted by Robert L. Michel, Editor, with James B. Powell, M.D. and Alan C. Nelson, Ph.D. These individual interviews were combined for clarity to show the uniformity of business strategies and outlook shared by both men. Dr. Powell and Dr. Nelson reviewed and approved the resulting "three-way-interview" which you are about to read.

EDITOR: Gentleman, could you please explain why this merger between **AutoCyte, Inc.** and **NeoPath, Inc.** is taking place?

DR. POWELL: In simplest terms, officers and directors at both companies realized that joining forces would allow us to almost immediately bring to market a single, automated solution for Pap smear preparation and screening. We believe this is what customers want.

EDITOR: You describe a short-term goal which allows you to market your "integrated" system to clinical laboratories immediately. What long-term business strategies bring your two companies together? Those are the real keys to understanding this merger.

DR. POWELL: At AutoCyte, we've always believed that an effective cytology system must address, in a comprehensive way, all the sources of error in the current technology. This includes sampling, preparation, and screening. Image analysis is a key element in standardizing quality and eliminating screening errors. The merger brings together AutoCyte's improvements to sampling and preparation with NeoPath's comprehensive foundation of imaging technology.

DR. NELSON: Pathologists and cytologists can look beyond the immediate question of whether the AutoPap® Pap smear screener can do a better job than traditional methods. Actual clinical experience is providing that answer. But before cytology and anatomic pathology laboratories can move to a higher level of adding value to physicians and patients while controlling costs, they must have the capability to integrate and handle information.

DR. POWELL: Which is why AutoCyte has always believed digital imaging of cytology slides to be the end game. AutoCyte and NeoPath are joining forces to develop a fully integrated technology package that does five things for clinical laboratories.

EDITOR: Share these, please.

DR. POWELL: First, we believe that liquid prepation, performed on automated equipment, will both enhance Pap smear screening and offer cost benefits. Second, the ability to totally automate the primary screening of Pap smears continually improves with each enhancement to existing technology. Further, automated image analysis improves and builds upon the best of human screening alone.

DR. NELSON: The next three areas are what most laboratorians overlook with today's technology capabilities. These are essential to understanding why our two companies believe the merger is a smart strategy.

DR. POWELL: Third, once screening is complete, the specimen must be archived.

AutoCyte-NeoPath Merger Creates Tough Competitor

When the merger between AutoCyte, Inc. and NeoPath, Inc. occurs later this year, it creates the company to beat in automat-ed cytology.

It also leaves ***Cytyc Corporation*** *as the only other competitor offering an FDA-approved product in the marketplace. Cytyc offers a product that automates the preparation of Pap smears, but sells nothing that automates primary screening. That may put Cytyc's single function product at a disadvantage to the integrated preparation-screening package that AutoCyte and NeoPath expect to create from their respective PREP and AutoPap Systems.*

MorphoMetrix Technologies, Inc. *of Toronto, Canada is developing an auto-mated system that will use liquid prep and digital imaging to prepare and screen Pap smears. However, this company has not yet begun the formal application process with the FDA. Also, it remains to be seen whether MorphoMetrix's technology infringes any of the extensive patents now held in common by AutoCyte and NeoPath.*

Currently this is done with glass slides. However, imaging technology can now allow a laboratory to archive an electronic record of the specimen. Fourth, clinical laboratories will need to serve physicians with telecommunication and telemedicine capabilities. Glass slides can't do this. Electronic archives can. Fifth, there is a growing demand to match cytology and anatomic pathology images to a patient's total health record as archived by hospitals and physicians.

EDITOR: Wow! You are describing an instrument suite which goes beyond simply automating Pap smear preparation and primary screening.

DR. NELSON: That's correct. As manufacturers of products designed to help laboratories add value in the managed healthcare environment, our companies were independently working toward very similar solutions to that five-step integrated capability just described by Dr. Powell.

EDITOR: In other words, from different technology platforms, both companies were actually trying to design something that would end up doing the same thing for clinical laboratories.

DR. NELSON: More or less true.

DR. POWELL: I agree, in terms of what kind of products our individual companies were planning to create during the coming years.

EDITOR: Dr. Powell, before we leave this concept of what I'll call the "integrated cytology system," could you clarify for DARK REPORT clients your vision of the laboratory of the future as it pertains to cytology and anatomic pathology?

DR. POWELL: Robert, in our past discussions I've indicated to you that we believe there will be ongoing consolidation of both clinical laboratories and anatomic pathology practices.

EDITOR: Yes, but given the widespread consolidation among commercial labs that has already occurred, why do you believe there will be further laboratory consolidation?

DR. POWELL: Good question. First, in the commercial arena, past consolidation created today's *existing* system of regionalized, high-volume laboratories. The three national laboratories, **LabCorp**, **Quest**, and **SmithKline**, are examples of this, along with a number of regional independent labs. Obviously these labs, still performing cytology with traditional, manual procedures, represent *existing* demand for an automated cytology solution, as well as demand for other pathology solutions.

EDITOR: Yes. That's definitely a group of laboratories with unmet

needs for automating cytology and Pap smear screening.

DR. NELSON: Precisely. NeoPath designed the AutoPap System with this particular market in mind.

EDITOR: Which is why the first buyers of the AutoPap Primary Screening Systems were laboratories like **SmithKline Beecham Clinical Laboratories** *(see TDR, November 9, 1998)* and **Unilab Corporation**.

DR. NELSON: Yes. Each of the three national laboratories already performs roughly 5-6 million Pap smears annually. With the shortage of qualified cytotechs in some cities, such labs find AutoPap to be a viable solution, particularly if their volume of Pap smears is increasing in those same cities and they need to improve the productivity of Pap smear screening.

EDITOR: Okay. So one specific market is the commercial lab industry, which has already consolidated, for the most part. Dr. Powell, why is your business plan based on an assumption of continued consolidation?

DR. POWELL: We believe that consolidation of hospital laboratories and anatomic pathology practices will continue in response to a variety of clinical and economic forces. This will increase the number of laboratories doing high volumes of testing. These types of laboratories will need to automate what are now manual procedures.

EDITOR: Do both of you believe there will be 1) continuing; and 2) extensive, consolidation of hospital laboratories and pathology practices?

DR. NELSON: Yes. Keep in mind that overall reimbursement for laboratory testing and anatomic pathology procedures is not keeping pace with the rate of inflation. This is one fact which encourages consolidation. Also, laboratories use consolidation to access economies of scale, thus lowering costs.

DR. POWELL: Let me add that cost pressures and the need for increased diagnostic capability do give even modest-sized laboratories the incentive to investigate and acquire automation that promises extra efficiency.

EDITOR: What about clinical integration? As that occurs, it forces discrete providers to link into an information continuum...

DR. NELSON: ...Robert, that is perceptive, because it ties in with Dr. Powell's earlier comments about the downstream uses of electronic archiving and diagnostic information management of Pap smear, cytology, and pathology images.

EDITOR: Thus, when Dr. Powell mentioned that he's always felt imaging was the critical component, and end game, in the cytology/AP automation process, he's referring to the need for laboratories to be ready to store lab results, archive it in such a way that it can be retrieved, and pass it along the clinical pathways in such forms that other users can generate useful clinical knowledge and utilization information from it. Do I understand this correctly?

DR. NELSON: Yes. That concept asks laboratorians to think in another dimension. Both NeoPath and AutoCyte are developing the capability to use this technology beyond the basic function of automating the preparation and primary screening of Pap smears. Our goal is that the systems be an integrated solution for preparation, more accurate diagnosis, analysis, archiving, and information exchange among providers.

DR. POWELL: Allow me to point out a significant benefit of an integrated system which can electronically archive Pap smears. Currently, all large laboratories have a problem in archiving glass slides. For example, remember the 6 million Pap smears that **Laboratory Corp. of America** does annually? LabCorp needs to archive those 6 million glass slides!

EDITOR: That's expensive.

DR. POWELL: Besides the expense, there is the problem of slide retrieval when the situation calls for a specific slide to be found or referred to another laboratory or diagnostic site.

DR. NELSON: Finding and referring archived glass slides is time-consuming, costly, and the retrieved slides frequently are not returned to their original place. They are also subject to degradation over time.

> ***"Without imaging, all you have is a slide. By imaging the Pap smear slide, you gain the improved ability to archive the slide, retrieve the specimen anytime, analyze the clinical data, and pass the specimen and results to other healthcare providers as required."***
>
> ***James B. Powell, M.D.***
> *President & CEO, Autocyte, Inc.*

DR. POWELL: That is why digital imaging of the specimen makes a lot of sense. It saves money on storage, it allows a faster retrieval when necessary, and it allows a copy of the electronic file to be distributed anywhere it might be useful. This is all available as a by-product of the image analysis process.

DR. NELSON: And it is why both NeoPath and AutoCyte are designing our various cytology screening systems to eventually meet laboratories' needs for storage, retrieval, and possible later electronic transmission of the specimen to other physicians.

DR. POWELL: There are still legal requirements that labs retain the glass slide. But archiving electronic data is now accepted in radiology. The same is begining to happen in pathology. We believe that cytology and pathology must move to image-based archiving to integrate with other sectors of healthcare.

EDITOR: Thus, one key to understanding this merger between AutoCyte and NeoPath is their common commitment to an integrated imaging information system. This was the common goal for each company's product design, even if their technology platforms and design philosophies were different.

DR. NELSON: That's a fair assessment. During the last six months a number of things caused our two companies to work closely together. That led us to realize there was more benefit in combining forces than to continue independently funding parallel research and development projects.

EDITOR: This spring AutoCyte purchased the patents and other intellectual property of **Neuromedical Systems, Inc.**, makers of the PapNet® System. Shortly thereafter I noticed announcements by AutoCyte and Neopath that they would share the intellectual property and that a clinical trial would commence to demonstrate AutoPap's effectiveness in screening liquid prep specimens from AutoCyte's PREP® System. *(See TDR, April 5, 1999.)* Were these the corporate exchanges that led to the merger decision?

DR. POWELL: Yes and no. Long term, we definitely agree on how cytology and pathology will evolve. Short term, both companies are prepared to move their products from a research/evaluation and early adoption phase to widespread clinical use. The other driver in this merger was the fact that AutoCyte now has FDA approval for our PREP System, an automated liquid prep system to be used in Pap smear preparation. NeoPath has FDA approval to use its AutoPap System as a primary screener. The merger allows us to quickly submit an FDA supplement for the combined use of these products to laboratories as a single automated solution.

EDITOR: Dr. Nelson, AutoPap is already in the marketplace. NeoPath

intentionally did not develop a preparation system. So why does NeoPath want to package its AutoPap System with AutoCyte's PREP System?

DR. NELSON: That's simple. As we went to customers to offer them an automated screening system, they told us they want to buy a single solution to Pap smears. That means preparation as well as screening. Pairing AutoCyte's PREP System, with NeoPath's Autopap System, allows us to provide that single solution.

EDITOR: But can PREP-prepared Pap smears be screened on AutoPap?

DR. NELSON: We have a clinical trial under way to demonstrate its ability to screen a PREP Pap smear. Once the trial is complete, we will file a supplement to our PMA with the FDA. Assuming that the FDA accepts the results of the clinical trial, then AutoPap and PREP can be sold as an integrated system. We already published some earlier study results which are encouraging.

DR. POWELL: This should take a few months to accomplish. In the meantime, each company has an FDA-approved system available to laboratories for immediate use. We are in the process of helping laboratories which currently own and use our PREP instruments for non-gynecological use to convert them to gynecological application. This is occurring as we speak.

EDITOR: Could either of you say something about any unexpected benefits to a laboratory when it can eventually operate a PREP and AutoPap system together?

DR. NELSON: Using Pap smears prepared in the traditional manner, an AutoPap instrument can process at least 40,000 slides per year. Early indications are the AutoPap should be able to significantly increase that number using liquid prep Pap smears.

EDITOR: That certainly changes the economics for the laboratory. Why such a huge increase in productivity?

DR. POWELL: Using liquid preparation techniques on Pap smears generates a slide which is free of extraneous material. The target cells are presented with more uniformity. There is more consistency in the number of cells present than with manual prep methods, and they are placed within a smaller, predefined area on the slide.

DR. NELSON: What the liquid prep Pap smear presents to AutoPap is a slide which is not only more consistent but has significantly less data for the imaging system to capture and process.

EDITOR: So AutoPap takes less time to capture data from each liquid prep slide, and the software algorithms can crunch that data more rapidly.

DR. NELSON: True. And remember, there is a tremendous amount of data on a traditional Pap smear, up to four gigabytes per slide! For comparison, a liquid-based preparation slide would contain less than one quarter the amount of data. Another comparison involves a breast mammogram, which typically generates only about seven megabytes of data.

EDITOR: That means AutoPap can read a liquid-based preparation slide faster because it has fewer cells to capture and less raw data for the software to process. I must ask a logical question. Given this type of benefit, why hasn't **Cytyc Corporation**, makers of the ThinPrep® liquid prep system, done a clinical trial to show its compatibility with AutoPap?

DR. NELSON: That's a fair question. I will only say that our two companies have been in discussions during recent years about such a trial, and those discussions were not conclusive.

EDITOR: It seems to me that Cytyc has now missed an opportunity to position its preparation product as compatible with the AutoPap Primary Screen System. AutoCyte's PREP System is now the preferred partner, given the merger between AutoCyte and NeoPath.

DR. NELSON: No comment on that.

EDITOR: ThinPrep has a retail list price of $9.75, plus the cost of the equipment and added labor. In recent years, I've repeatedly heard that AutoCyte was expected to provide a liquid-based preparation system at a considerably lower cost per test than that of Cytyc.

DR. POWELL: That's our expectation.

EDITOR: Well, I know what the "per click" retail price of AutoPap has been. Several analysts tell me that they believe the combination PREP and Autopap instrument package will offer laboratories a cost-per-slide for prep and screen that is considerably less than Cytyc's suggested retail of $9.75 for liquid-based preparation alone.

DR. NELSON: We are not ready to publish our expected pricing nor discuss our pricing strategy. Among other things, the clinical trial involving PREP and AutoPap still remains to be completed. The merger must also take place before the companies can properly evaluate how to price the combined system when a laboratory buys it as a package.

EDITOR: Let me discuss the merger then. I know that both companies continue to experience cash burn. Slowing the drawdown on existing capital must have been one consideration in this merger.

DR. NELSON: Without question, combining the two companies and eliminating redundancies benefits us both. Total cost reductions related to the merger of approximately $6 mil-

Reimbursement Picture For Automated Cytology Expected to Evolve as Payers See More Claims

HOW TO GET PAID for new laboratory assays is the million-dollar question in the lab industry these days. In the past. as new cytology technology entered clinical use, the payment system was often not ready to respond.

Expect that to change in 1999 and 2000, for several reasons. First, laboratories already using the new technology, along with existing cytology vendors, provided a different level of input into the creation of new CPT codes for automated cytology procedures. These CPT codes became effective January 1, 1999.

While the AMA and HCFA were studying the new codes, input from the laboratory industry helped to structure the new codes so that payers recognized the clinical significance of these procedures. Effectively, this means that laboratories submitting claims under the new cytology CPT codes are finding it relatively easier to establish and clarify each payer's reimbursement policies.

Second, vendors established reimbursement SWAT teams to help labs educate payers about the new CPT codes and help them establish acceptable levels of reimbursement.

Third, the campaign to increase Medicare'reimbursement for traditional Pap smears has made the entire subject of women's health and automated Pap smear technology a more visible issue, requiring action by regulators.

Add to this mix a steady increase in the number of laboratories using automated cytology sytems and trying to bill for them, and it means that payers are finally responding. In fact, there is anecdotal evidence from the field which indicates that payers do not give automated cytology CPT codes much notice until they see a regular stream of claims for automated cytology procedures. At that point, payers, under pressure from labs and vendors, take steps to establish their reimbursement schedules for the new CPT codes.

lion per year have been planned by both companies already. That is significant. Plus, our pooled cash currently represents a war chest of more than $20 million.

EDITOR: Could you comment on the merger specifics?

DR. POWELL: This is a merger of equals. I want to stress that. Each company's stockholders will end up with about 50% of the shares in the combined firm. It is our intention to rename the company when the merger is complete.

EDITOR: What about management?

DR. POWELL: Dr. Nelson will be Chairman. I will be President. Each company will represent a division of the unified firm and will continue to operate and manufacture in existing facilities. The functional areas of the companies will be combined.

EDITOR: Could you speak to the sharing of intellectual property and the benefits you expect from that?

DR. POWELL: As you know, upon merging, we will have all the patents, patents pending, and intellectual property from AutoCyte, Neopath, and Neuromedical. This is an important resource and makes it easier for us to develop other applications of our imaging technology, software algorithms, and growing clinical data repository.

EDITOR: What about staff resources?

DR. POWELL: Some of the best Neuromedical scientists have joined us. We now have the intellectual brain trust from AutoCyte, NeoPath, and Neuromedical working together. We project a three- to four-year effort to develop and bring to market an integrated suite of instruments for Pap smear preparation, screening, archiving, and information processing.

EDITOR: Does this effort extend beyond Pap smears and cytology?

DR. POWELL: That is our intent. In earlier interviews, I've told you and readers of THE DARK REPORT that cytotechnologists and pathologists need tools which automate and support their clinical skills. *(See TDR, September 28, 1998.)*

DR. NELSON: Hematology underwent a similar technology development curve. Hemotechnologists no longer look through a microscope and count cells by hand. Now they are medical technologists who administer the effective operation of a variety of sophisticated instruments that offer diagnostic information unimagined during the days when blood was smeared on a slide so someone could manually count the cells.

EDITOR: So both you gentlemen expect to see your combined technology platform find application in other areas of cytology and anatomic pathology?

DR. NELSON: Yes, but those are plans for the future. Our immediate goal is to install products now approved by the FDA into the hands of cytology laboratories, where they can put them to useful work in gynecological applications.

DR. POWELL: I would only add that we at AutoCyte are excited to have FDA approval for our PREP System. As Alan says, the immediate objective of our combined companies will be to introduce PREP and AutoPap Systems into successful operation in as many laboratories as possible.

EDITOR: Dr.'s Powell and Nelson, thank you for sharing your thoughts and plans for automated cytology systems. Your candid comments are appreciated by clients of THE DARK REPORT. **TDR**

For further information, contact James B. Powell M.D. at 336-222-9707 and Alan Nelson, Ph.D. at 425-556-2950.

Labs on the Internet

Healtheon and WebMD Merger Portends Changes to Lab Testing

SO FAR CLINICAL LAB EXECUTIVES have yet to see any profound changes that Internet-based services might cause to existing laboratory practices and procedures.

That situation may change, however, with the merger of **Healtheon Corporation** of Santa Clara, California and **WebMD, Inc.** of Atlanta, Georgia. The merger is expected to occur during fourth quarter 1999.

Internet Transactions

Healtheon is a company which is developing the internet as a platform for transactions between all classes of healthcare providers, including payers. It intends to be the "copper wire" which carries information between payers, hospitals, doctors, laboratories, and other providers.

WebMD, on the other hand, is a company which originally set out to be a physicians-based service. It wanted to offer doctors a portal to access services, while providing subscription-paid information resources.

Healtheon signed a contract with **SmithKline Beecham Clinical Laboratories** (SBCL) in January 1998 to manage its electronic order entry and results reporting functions to high-volume lab clients. This agreement was updated in February 1999.

Automate SBCL's Reports

The updated agreement is a five-year pact for Healtheon to automate and expand the exchange of information between SBCL clients and SBCL. Effectively, it designates Healtheon to replace in-office teleprinters with Internet-based communications capability.

Therein lies the importance of the Healtheon–WebMD merger for clinical laboratories. Healtheon has been connecting payers and providers. This year it will process 1 million E-commerce transactions per and 25 million clinical transactions. Meanwhile, in its first ten months of business operations, WebMD has 54,000 physician subscribers. These are fast-growing enterprises.

Healtheon–WebMD wants to eventually reach into every physician transaction. That includes claims processing, patient record access, transcription service, supply orders, *and*...laboratory orders! Effectively, this means there is an independent company out there working on methods to connect clinical laboratories with physician offices.

SBCL An Earlier Player

Obviously, SBCL got a jump on this project with its Healtheon agreement. THE DARK REPORT would expect that hospital laboratories which use SBCL as a reference lab will get to see, first-hand, how Healtheon handles moving information back and forth between SBCL and its clients.

In the meantime, THE DARK REPORT recommends that laboratory executives and pathologists begin to learn more about Healtheon and WebMD. Not only do these companies have their targets set on changing the way physicians order tests from the lab, but they have huge amounts of capital available to insure that it happens! **TDR**

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

One of dermatopathology's academic giants has been snared by a pathology PPM. A. Bernard Ackerman, M.D., will leave his professor post at **Jefferson Medical College** in Philadelphia to work with **AmeriPath, Inc.** and help it develop a dermatopathology center in New York City. It is to be called the **Ackerman Academy of Dermatopathology.** AmeriPath's goal is to develop a licensed, state-of-the-art, independent outpatient laboratory specializing in dermatopathology which Dr. Ackerman will use to establish an accredited dermatopathology fellowship training program.

MORE ON...AMERIPATH

AmeriPath is the largest pathology physician practice management (PPM) company in the country. Its business strategy has included the acquisition of independent dermpath practices from Florida through Texas and the Midwest. Dr. Ackerman's relationship is important to Ameripath because, with his international reputation, it allows AmeriPath to begin building a pathology "brand name" for dermatopathology.

CLMA RECOGNIZES PATH MEDICAL LABS FOR MANAGEMENT EXCELLENCE

More recognition for one of our favorite business models of good laboratory management. At **CLMA's** annual conference in Dallas last month, **Pathology Medical Laboratories, Inc.** (PML) of La Jolla, California received CLMA's Betty Martin Award. This award "recognizes innovative leadership in any of six [management] categories." It cites PML for nearly 30 years of "high moral and ethical standards in innovation to become San Diego's leading regional laboratory."

ADD TO...PML AWARD

Clients and readers of THE DARK REPORT will recall that PML's Chairman and CEO, Phillips S. Gausewitz, M.D. is one of our lab industry ***Movers and Shakers*** for this year. *(See TDR, March 15, 1999.)* Dr. Gausewitz is a shrewd businessman who blended his pathology skills with a "customer-first" management approach that has made PML a profitable lab even in San Diego's competitive managed care marketplace. His leadership at PML demonstrates that clinical laboratories do not have to chase below-cost managed care contracts to survive.

Another pathology-based practice management firm is now in the marketplace. **US Pathology Labs, Inc.** of Irvine, California announced the signing of a contract to build and manage an anatomical pathology laboratory for **University Pathology Associates** (UPA). This 36-pathologist group serves hospitals that are part of the **University of Southern California School of Medicine** in Los Angeles, California.

Beckman Coulter, Inc. has been busy positioning its new generation of instruments with a number of group purchasing organizations. Announced during June were updated pacts with **AmeriNet, Inc.** (June 14), **MAGNET** (June 15), and **Novation** (June 28). Beckman Coulter executives Albert Ziegler and Jeff McHugh estimated that the three agreements would generate sales of about $675 million during the term of the contracts.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, August 9, 1999

THE DARK REPORT

UPCOMING...

- *"Branding" Anatomic Pathology Services Emerges as an Industry Phenomenon.*
- *Hospital Lab Director Outsources Sales, Billing, Courier...and Makes Big $'s!*
- *Updates on the Sideways Acquisition of SBCL by Quest Diagnostics.*
- *Confessions of a Former TLA Sales Rep: What Vendors Didn't Want Labs to Know.*