Volume IV, Number 2 Monday, January 27, 1997

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Plenty Of Money To Go Around

Despite what managed care is doing to clinical laboratories, money abounds to sell more goods. In this issue, you will read about how **AmeriPath, Inc.** is about to raise $71.7 million while **Cytyc Corp.** intends to generate $48.2 million in its second public offering in 12 months.

The list of laboratory-related companies which raised money during the last year is extensive. It includes specialty testing companies like **UroCor, Inc.** and **Impath, Inc.**, as well as technology companies such as **NeoPath, Inc.** Even clinical laboratories succeeded with offerings. **Universal Standard Medical Laboratories**, **Unilab, Inc.** and **Quest Diagnostics, Inc.** all tapped public markets for additional funds during the last 12 months.

The practical impact of all this money will be seen when sales representatives from these companies call upon you at your laboratory and want to sell you this "hot technology." Cytology provides a good example. Since FDA approval in 1995, both NeoPath (AutoPap 300) and **Neuromedical Systems** (PapNet) launched aggressive sales blitzes. As pointed out in our story on page 15, Cytyc will use $25 million from its latest offering to market ThinPrep in the United States. Cytyc already has as many as 50 sales representatives hired and prepared to hit the field. Expect them to be joined by sales reps from **AutoCyte, Inc.** and **Accumed International, Inc.** when both companies decide that their cytology products are ready for introduction into clinical usage.

If you feel beleaguered by all the sales representatives who stop by your laboratory to present their products, understand that they represent the future of laboratory medicine. Even as hospital laboratories consolidate and downsize, new jobs are opening up with these technology companies. It may be that one day, your experience and knowledge about laboratory practices gains you a lucrative position with just such a company. Headhunters told us in a recent issue *(See TDR, November 4, 1996)* that employment opportunities are abundant for laboratorians who look for work outside the laboratory.

That is the reason we keep you informed about the business plans of these emerging laboratory technology companies. Whether they succeed or not, their influence on laboratory operations and profits is immense, and their potential to transform clinical laboratory practices should not be overlooked. TDR

AmeriPath To Go Public, Files SEC Registration

Florida firm seeks to raise $71.7 million by selling 36% of the company's shares

CEO SUMMARY: AmeriPath's Initial Public Offering will make it the first publicly traded physician practice management company specializing in pathology. It represents a unique attempt to restructure traditional pathology practices to meet the needs of managed healthcare organizations.

PATHOLOGY ENTERS A NEW ERA when **AmeriPath, Inc.** completes its proposed Initial Public Offering (IPO) during the next 30 days.

With the acquisition of several pathology practices in the last quarter of 1996, Florida-based AmeriPath now represents $82 million in annual revenue. Currently there are 12 pathology practices owned by or affiliated with the AmeriPath organization. The company intends to acquire more. Future acquisitions will be funded by money raised from the IPO.

The public offering seeks to raise $71.7 million. A total of 6.2 million shares will be available. Of that, 500,000 shares are currently owned by **Summit Partners**, the venture capital group in Boston which helped launch AmeriPath.

AmeriPath's arrival as a public company will force pathologists to compare the professional practice model represented by Ameripath against current forms of pathology organizations. Because of the groundbreaking nature of AmeriPath, it is already a much discussed development in the pathology world.

During the last two years, AmeriPath used cash, notes and stock to acquire 12 practices. Most are located in Florida, but others are in Texas, Ohio, Alabama and Kentucky. *(See complete list of pathology practices on page 7.)* From company documents, it appears that the cash portion of these purchases was financed with credit extended by a bank syndicate led by **First National Bank of Boston**.

AmeriPath sprang from a company called **American Laboratory Associates**

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

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, and CFOs 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.

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

SUBSCRIPTION TO the Dark Intelligence Service, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $10.80 per week in the US, $11.40 per week in Canada, $12.45 per week elsewhere (billed semi-annually).

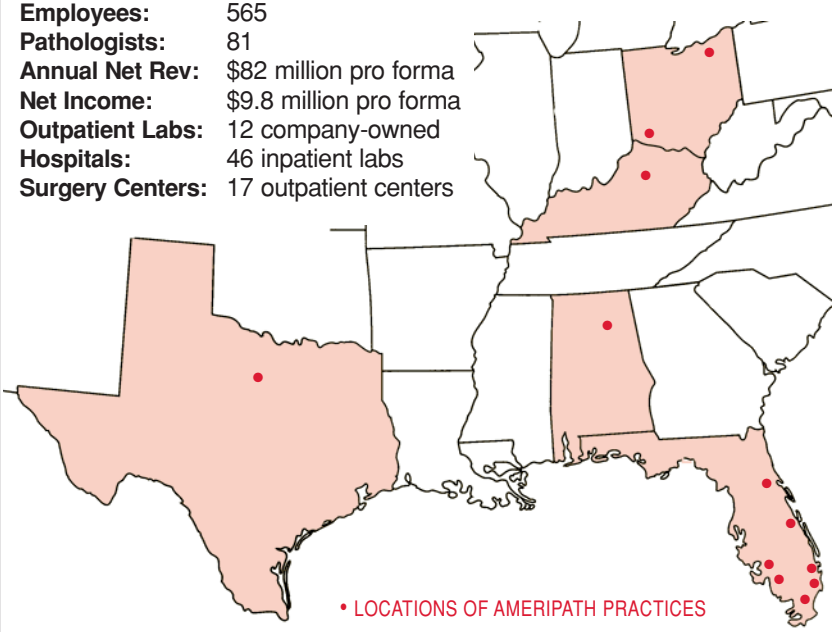
NO PART of this Intelligence Document may be printed without written permission. Intelligence and information contained in this Report are carefully gathered from sources we believe to be reliable, but cannot guarantee the accuracy of all information.

© The Dark Group, Inc.1997. All Rights Reserved.

AmeriPath, Inc.

At-A-Glance

Stock Symbol:	PATH
Stock Exchange:	NASDAQ
Headquarters:	Riviera Beach, FL
IPO Offering:	6.2 million shares
Total Shares:	17 million
Employees:	565
Pathologists:	81
Annual Net Rev:	$82 million pro forma
Net Income:	$9.8 million pro forma
Outpatient Labs:	12 company-owned
Hospitals:	46 inpatient labs
Surgery Centers:	17 outpatient centers



(ALA) in Fort Lauderdale, Florida. Owners of ALA were Evangelos Poulos, M.D., Michael Demaray, M.D. and A.P. Kowalczyk, M.D. Together with Thomas Roberts and E. Roe Stamps of Summit Partners, they put together the concept of a pathology-based physician practice management company in 1994.

James New was brought aboard as President in January 1996. AmeriPath itself was formed as a holding company in February 1996. At that time, only two pathology practices were owned by the company.

During the balance of 1996, AmeriPath's key executives worked swiftly. Ten more pathology practices were added between June 1996 and November 1996.

As of year end, AmeriPath counted 81 pathologists in the system, with 77 board certified, and 4 board eligible in anatomic pathology. From this group, 39 are also board certified in the subspecialties of dermatopathology, hematopathology or cytopathology.

AmeriPath provides pathology services through 12 outpatient pathology laboratories owned and operated by the company, 46 hospital inpatient laboratories and 17 outpatient surgery centers.

"There are some interesting aspects to Ameripath," stated a consultant who advises pathology prac-

tices on business and financial strategies. "As I compare the revenue base and number of pathologists to the industry norm, I see that AmeriPath is generating about $82 million in annual revenues from their 81 pathologists.

"This means that AmeriPath has pathologists who generate unusually high volumes of revenue, since they average about $1 million per pathologist. That top line number is commiserate with what a dermatopathologist typically generates. I would estimate that the national average is probably close to $500,000 in revenue per pathologist per year."

Business Perspective

"I consider this significant from a business perspective," he continued, "because I would want to learn more about how pathologists at AmeriPath will sustain an average revenue of $1 million per pathologist per year. If they can successfully maintain that over several years, such productivity would definitely give them a competitive advantage."

AmeriPath's business plan is ambitious. The company intends to evolve into a national provider of pathology services. It will accomplish this by developing regional pathology networks. Because it already has seven pathology practices in Florida, the first regional network will be in that state.

Funding Acquisitions

Further acquisitions of pathology practices will probably continue to be funded with a combination of borrowed cash (from the credit line) and stock. Although AmeriPath expects to net $71.7 million from the sale, virtually all that money is earmarked. It will retire notes, pay accrued dividends on preferred stock and pay down $59.6 million of the outstanding $81.7 million in bank debt.

In fact, after the offering, the balance sheet projects that AmeriPath will have only $4 million in cash and $13.3 million in accounts receivable. Total assets project to be $143 million. The bulk of assets are goodwill, at $58.5 million, and "identifiable intangibles" of $59.9 million. "Identifiable intangible assets" relate to hospital contracts, physician referral lists and laboratory contracts obtained in the recent acquisitions.

Columbia Contracts

Another interesting aspect to AmeriPath is the number of contracts with hospitals owned by **Columbia/HCA Healthcare Corporation**. Of the 46 hospital contracts held by the subsidiaries, 20 are with Columbia hospitals. On the pro forma statement, those Columbia hospital contracts account for 24.5% of AmeriPath's net revenues.

Columbia represents both a threat and an opportunity for AmeriPath. The threat comes from Columbia's ability to move the business away from AmeriPath, thus depriving the company of up to one quarter of its revenues.

The opportunity comes from the existing relationship with Columbia hospitals. That may make it easier for AmeriPath to increase the number of pathology contracts it holds with Columbia.

No Easy Road

There is no easy road for AmeriPath to follow. Although the concept of a physician practice management company has proved successful, there has never been a publicity traded company organized around pathology.

Because of this fact, AmeriPath will have a high profile in the pathologist community. Pathologists throughout the country are keenly interested in what happens to AmeriPath. Should AmeriPath prove successful, expect many competitors TDR

(For further information, contact AmeriPath, Inc. at 561-845-1850.)

AmeriPath's Strategies For Business Success

Pathology firm plans to organize around concept of regional pathology networks

CEO SUMMARY: Two fascinating aspects about the AmeriPath story are: 1) the strategy to boost share values; and 2) the strategy to develop profitable pathology revenues. With managed healthcare transforming pathology at an astounding rate, will AmeriPath succeed in both strategies?

DURING THE LAST YEAR, intense curiosity swirled about **AmeriPath, Inc.** Pathologists heard plenty of rumors but learned few details about the Florida-based company.

Such curiosity was warranted. Physician incomes are dropping for well-known reasons. Reimbursement levels are in decline. Capitated agreements push risk onto pathologists. Hospital acquisitions trigger pathology practice consolidations. Cost-cutting efforts by individual hospitals further reduce pathology revenues.

As pathologists watched their revenue sources come under the cost-cutting axe, they also saw the phenomenal success of those physician management companies which went public. Such companies as **Phycor**, **MedPartners**, **Physician Reliance Network** and others have grown at phenomenal rates.

These companies enriched the primary care and specialist physicians who sold their practices in exchange for stock and other consideration. They also made tens of millions of dollars for investors. As a result, one of the hottest industry segments on Wall Street is the physician management company. Some 22 companies now crowd the category.

Share prices in this segment trade at an *average* multiple of 23.5 times EBITDA. (EBITDA stands for "earnings before interest, taxes, depreciation and amortization" and is widely used to measure cash flow.) The EBITDA multiple of 23.5 is one secret behind the AmeriPath strategy to boost share value.

Share Price Strategy

Were AmeriPath share prices to achieve the same EBITDA multiple as the average physician management company, then profits would be substantial. The arithmetic reveals how this occurs.

According to company documents, Ameripath spent approximately $110 million in stock, notes and cash to acquire the 12 pathology practices. Based on four-year contingency payments, as much as $40 million more could be paid to those 12 practices. This means that it cost AmeriPath approximately $150 million to acquire

the existing $82 million in annual company revenues.

Assume that the Initial Public Offering (IPO) sells out at $14.00 per share. Based on figures in the company's prospectus, it would appear that $14.00 per share would be an EBITDA multiple of around 13.5.

Should AmeriPath successfully sell all 6.2 million shares at $14.00... market capitalization of AmeriPath would be $238 million!

Were AmeriPath's profit margins to remain at the current level, and if Wall Street bid AmeriPath shares to the 23.5 EBITDA multiple, that would create a share price of $24.00.

With 10.8 million of the company's 17 million shares still in the hands of the venture capitalists and the original pathologist-stockholders, that represents a potential gain of almost $110 million dollars! The actual gain is even larger, because many of the shares issued in pathology practice purchases were at share prices under $10.00.

For those who ask the question about how wise it was to pay as much as $150 million for $82 million in annual revenues, the answer is simple. Should Ameripath successfully sell all 6.2 million shares to the public at $14.00 per share, there would be a total of 17,051,356 shares outstanding. Multiply that by $14.00, and the market capitalization of AmeriPath would be $238 million!

Money Magic

This is money magic, practiced the Wall Street way. By understanding this arithmetic, it is easy to know why the organizers of AmeriPath feel confident that their hard work and entrepreneurial risk will pay off.

Although the arithmetic makes this look easy, there is a sizeable downside. Much hard work lies ahead for AmeriPath. Investors will only bid up the share price of AmeriPath if they are confident that AmeriPath can deliver solid, consistent revenue growth and increased earnings.

This means that AmeriPath must demonstrate to investors that their pathology practices can generate profits equal to, and preferably greater than, existing private pathology practices.

It is this fact which generates controversy among pathologists throughout the country. The most common question they ask each other is, "Will a pathologist on salary in a public company produce more work than a pathologist who is a full partner in private practice?"

That is one of the great unanswered questions in pathology. It is precisely why pathologists will closely watch what AmeriPath does, and how well AmeriPath does it.

Revenue Strategy

The business plan that AmeriPath intends to pursue is that of integrated regional pathology networks. Florida will be the protype network, since AmeriPath already has seven pathology practices in the state employing 62 pathologists.

The foundation for this pathology network is substantial. Besides the six outpatient laboratories, AmeriPath's Florida region has contracts with 29 hospitals and 17 outpatient surgery centers. AmeriPath has ten sales representatives who are actively soliciting new business for the local practices.

In offering regional pathology services, AmeriPath was successful in expanding an existing anatomic pathology services contract with **SmithKline Beecham Clinical Laboratories**. The original contract was for exclusive

pathology services in five Florida counties. The expanded contract now includes 57 of Florida's 67 counties.

Building on this early success will require skillful management and focused effort. AmeriPath's business strategy must accomplish two things to create the earnings growth necessary to support higher share prices.

First, AmeriPath's pathologists must demonstrate sustained productivity, for this is a major source of operating profit. Second, the sales force has to generate new revenue without discounting prices. Clinical laboratories have already demonstrated the near impossibility of that fact in today's managed care environment. Should AmeriPath succeed in both areas, it fully deserves the financial success which will result. TDR

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

AmeriPath's Pathology Line-Up

List Of Acquired Practices

PRACTICE	LOCATION	PHYSICIANS	PERSONNEL	CONTRACTS	LABORATORY NET REVENUE (IN THOUSANDS)
American Laboratory Associates	Fort Lauderdale	6	127	--	$16,024
Cutaneous Pathology & Immunofluorescence Laboratory	Beachwood	3	16	--	$3,798
D&P Pathology	Fort Lauderdale	9	9	3	$ 2,548
Derrick and Associates Pathology	Orlando	24	143	14	$21,706
Florida Pathology Associates	Miami Beach	2	14	1	$ 3,055
Freeman-Cockerell Laboratories	Dallas	1	40	--	$ 3,160
Gulf Coast Pathology Associates	Cape Coral	5	31	3	$ 8,786
Pathology Associates	Lexington	8	58	16	$ 4,934
Richfield Laboratory of Dermatopathology	Cincinnati	3	32	--	$ 6,202
Drs. Seidenstein, Levine & Associates	Fort Myers	9	42	5	$ 6,181
SkinPath	Birmingham	3	20	1	$ 1,847
Volusia Pathology Group	Ormond Beach	7	33	3	$ 5,825
Totals		**80**	**565**	**46**	**$84,066**

Three Public Laboratories Choose New Presidents

LabCorp, Unilab and Meris start 1997 by bringing in new executive leadership

CEO SUMMARY: Three public laboratories experiencing serious financial pressure enter the new year with a change in presidents. It is a sign that stockholders and creditors are growing increasingly restless with these organizations' inability to earn satisfactory profits.

Turnover among chief executive officers is usually not a good sign. During the last 45 days, three public laboratories issued formal announcements that their existing president was stepping down and a new president would assume duties.

First to name a new president was **Meris Laboratories** of San Jose, California. On December 12, 1996, Meris released a short statement to the public stating that William McCormick would assume duties as President and Chief Operating Officer. He replaces James Neeley, M.D. Neeley had resigned in late October 1996

LabCorp Next

Next was **Laboratory Corporation of America**. On January 7, 1997, LabCorp announced that Thomas P. Mac Mahon would replace James B. Powell, M.D., effective on that date.

Rounding out this series of announcements was a statement by **Unilab, Inc.** of Tarzana, California. Issued on January 20, 1997, it stated that David Weavil would become Chairman, President and Chief Executive Officer. Current CEO Andrew Baker was departing to assume duties with another company.

Despite the fact that all three laboratories are changing their chief executive officers, each has different reasons for seeking a new president. What is noteworthy is that these events are a consequence, directly or indirectly, of the poor financial performance of the three laboratories.

No Easy Solution

There is no easy solution to the problems challenging all three laboratories. Their management strategies to regain profitability will teach the industry valuable lessons about the right and wrong ways to respond.

When Meris Labs filled the open position of President, they picked someone from outside the industry. Most recently William McCormick had been President and CEO of an electronic claims processing service for healthcare providers.

At Laboratory Corporation of America, the departure of current president James B. Powell, M.D., caps a lengthy career in the laboratory industry. Dr. Powell founded the orig-

inal laboratory which eventually was acquired by **Hoffman-La Roche, Inc.** This laboratory became known as **Roche Biomedical Laboratories Inc.** and was later merged with **National Health Laboratories** in 1995 to form LabCorp.

Powell is leaving to become Chief Executive Officer of **AutoCyte, Inc.** This company was recently spun off from Roche and is developing automated Pap smear technology.

Powell's replacement lacks the extensive hands-on operating experience which Powell accumulated. Thomas Mac Mahon's entire career has been with Roche since his graduation from college in the late 1960s. He became a member of Roche's Worldwide Diagnostics Executive Committee. As a member of this committee from 1988 to 1995, he had oversight responsibility for Roche Biomedical Laboratories.

After LabCorp Merger

After the merger forming LabCorp, Mac Mahon served as Vice Chairman until he was named Chairman in April 1996. In contrast to Powell, who had first-hand experience in all phases of clinical laboratory operations, Mac Mahon has more of a "board of directors" perspective. Possibly his diagnostics experience may help point LabCorp towards other business opportunities besides clinical testing.

Events currently unfolding at Unilab will be intriguing to watch because of the change in corporate cultures. Departing CEO Andrew Baker originally came from **MetPath** (now **Quest Diagnostics Inc.**). Incoming CEO David Weavil was, until recently, Executive Vice President and Chief Operating Officer at LabCorp.

Weavil's Resignation

Weavil resigned in early December 1996. His departure was apparently related to LabCorp's $187 million settlement with the federal government, but details behind this aspect of the transaction have never been made public.

Weavil has a reputation for strong operations skills. Unilab has need of such skills. The $200 million laboratory is working to bring its statewide operations infrastructure onto a common system. Weavil will face some tough challenges, because Unilab's operating profit margins continue to erode in the face of California's aggressive managed care market.

All three incoming CEOs face daunting challenges. With the laboratory industry continuing to encounter shrinking reimbursements and declining test utilization, financial success may prove to be an elusive goal. TDR

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

High Turnover Among Laboratory Presidents

Poor financial results at many labs threaten job security of the top post. Here's a list of CEO/President changes during the last 18 months:

Laboratory	Date	Incoming	Outgoing
Unilab, Inc.	Jan, 97	David Weavil	Andrew Baker
LabCorp	Jan, 97	Thomas Mac Mahon	James B. Powell, M.D.
Meris Labs	Dec, 96	William McCormick	James Neeley, M.D.
Physicians Clinical Labs	Nov, 96	Marvin Feigenbaum	Nate Headley
Universal Standard ML	Mar, 96	Eugene Jennings	John Watkins
SmithKline Beecham CL	Mar, 96	Tadataka Yamata, M.D	Vickery Stoughton
Meris Labs	Dec, 95	Jerry Cullen	James Neeley, M.D.
Lab*One*	Oct, 95	Burt Hood	Thomas Grant, II
Corning/Quest	May, 95	Ken Freeman	Randy Thurman

Laboratory Trade Group Launches New Activities

American Clinical Laboratory Association seeks to increase member, industry support

CEO SUMMARY: Long overlooked by most of the laboratory industry, ACLA may be in the process of revolutionary change. Since David Sundwall, M.D., became President, ACLA has taken a more assertive stance on a wide variety of issues which affect all laboratories, not just ACLA members.

LONG CONSIDERED by most laboratory executives as a tight clique for the large commercial laboratory organizations, the **American Clinical Laboratory Association** (ACLA) has a new look and a new direction.

Under the guidance of President David N. Sundwall, M.D., ACLA is undertaking a variety of projects which cut across all boundaries in the clinical laboratory industry.

"In the two years since my arrival at ACLA, the laboratory industry has experienced extraordinary financial and regulatory pressure," said Sundwall. "Such pressures forced both ACLA and its members to address a variety of issues that were of little concern just a few years ago."

ACLA was traditionally viewed as the trade association which represented interests of larger commercial laboratories. "At one time there were eleven members. Mergers and acquisitions reduced that number, but with new laboratories, membership now totals nine," explained Sundwall.

"What we have discovered is that changes to healthcare caused ACLA to address important issues which are of concern to all clinical laboratories. This includes hospital labs and small independent laboratories as well as the large commercial organizations which comprised our original membership."

> ***"I can't imagine anything that ACLA's done which doesn't apply to most clinical laboratories and hospital laboratories."***
>
> ***—David N. Sundwall, M.D.***

Sundwall's access to events in Washington, D.C., combined with his daily interaction with a significant cross section of influential laboratory executives, gives him a unique perspective on the problems troubling clinical laboratories throughout the United States. Sundwall's observations and opinions provide thoughtful insights for laboratorians seeking to better understand today's market environment.

"Obviously the one subject which dominates the agenda of large laboratories is the ongoing investigation into laboratory billing practices and

its effect on how these laboratories perform testing and bill for services.

"After three and four years of investigations, most of the outstanding subpoenas will be resolved. However, one consequence is that the entire laboratory industry suffers from the impression that they have been 'doing bad things,'" he continued.

"This perpetuates a vicious circle. The government now considers previous activities as inappropriate. Most labs cannot fight these claims. In settling, the government just augments their position. It isn't fair, and both small labs and big labs are caught up in this mess."

Proactive Efforts

"This caused ACLA to identify a number of areas where proactive efforts would pay big dividends," stated Dr. Sundwall. "For example, in addition to government relations, we realized that we needed to do a better job of public relations. Now we have an advisory group which looks for opportunities to present our position to physicians, patients and others who should understand more about laboratory testing and its value."

ACLA advisory groups and members also invest considerable time in working with medicare carriers throughout the country. "Obviously the entire clinical laboratory industry is frustrated with the lack of clear direction and inconsistency of application from one carrier to another," noted Dr. Sundwall.

Carrier Meetings

"Our Billing and Reimbursement Advisory Group is meeting with carriers. This is the front line in the fight to gain clear understanding and agreement about what to code, how to code it and what documentation for medical necessity should be provided.

"We are discovering that personal interaction makes a difference. Medical directors of the carriers play an important role in making decisions about payment policies," he continued. "They cherish their autonomy and the **Health Care Financing Administration** (HCFA) gives them a certain freedom to interpret regulations according to their local needs. By meeting with these people and their staff, we are able to help them better understand how their decisions impact clinical laboratories.

"For ACLA, this was a deliberate change. We moved our total focus away from Congress. Now we tailor our message to the Medicare carriers. In every instance where we have met key individuals at a carrier, we get clarity on what they expect. In turn, we are able to educate them on some of the logistical problems we've encountered."

ACLA Members:

Acadiana Medical Laboratories
Lafayette, LA

ARUP Laboratories
Salt Lake City, UT

Quest Diagnostics Inc.
(Formerly Corning Clinical Labs)
Teterboro, NJ

Laboratory Corp. of America
Burlington, NC

LifeChem Laboratory Services
Northvale, NJ

Path Lab, Inc.
Portsmouth, NH

SmithKline Beecham Clinical Laboratories
Collegeville, PA

Spectra Laboratories
Fremont, CA

DCI Laboratories
Nashville, TN

"After meeting with the carriers and developing clarity for the issues under discussion, ACLA takes that information and produces what we call a 'Practice Advisory,'" he continued. "This provides background on the issue, an analysis of the relevant points, and an advisory of the appropriate action which a laboratory or physician should take to comply with this particular issue."

Interaction With Carriers

ACLA's interaction with the individual Medicare carriers is a direct consequence of early meetings between HCFA and ACLA. "When I first came aboard," explained Dr. Sundwall, "we met with HCFA and requested that they become more active in educating both carriers and physicians about policies involving laboratory testing. HCFA's response was 'That is your job. We don't have the budget for that.'

"When it was clear that HCFA was not going to mount an effective education campaign, we decided to take the initiative, meet with the carriers and provide our members and the laboratory industry with appropriate information. All our policy publications have been reviewed and approved by HCFA."

Important Issue

Another important issue where ACLA is in the forefront is LOINC. "As an acronym, LOINC sounds strange," said Sundwall. "It stands for Logical Observation Identifier Names & Codes database. This is an effort to standardize the coding and reporting of laboratory test results.

"We see this as a critical initiative for the laboratory industry. The electronic exchange of laboratory data across laboratories, hospitals, managed care organizations, physicians' offices and government agencies is critical.

"The goal is to get a uniform standard not only in this country, but in Canada and Europe as well," he explained. "ACLA's endorsement of LOINC means that up to 60% of the nation's independent laboratory testing volume will eventually use this format. That commitment by ACLA members is already convincing other segments of the healthcare industry to adopt a uniform standard. We think we hit a home run with this, and we are promoting it as an international language with some success."

Clearly Sundwall's discussion of ACLA projects indicates that the association is expanding far beyond its historical watch on Washington, D.C. Part of this change is attributed to Sundwall's unique background as an association president.

"It is important to understand that I am a practicing physician. I see patients every week on a voluntary basis. Because of that, I have an absolute appreciation of the value of laboratory data."

Sundwall's Perspective

Sundwall's perspective as a physician intrigued ACLA. The organization recognized that a physician could communicate the industry's unique role in healthcare with added credibility.

"One thing I've helped with is to strengthen communication with the physician community." said Dr. Sundwall. "I have good relationships with the **American Medical Association** (AMA). I am also improving relationships between ACLA and the **College of American Pathologists** (CAP).

"Physicians now realize that laboratory issues are becoming a greater hassle. Because of this fact, they increasingly welcome a partnership with us to the extent we can get relief from regulatory burdens.

"Remember, the requirements for diagnosis coding originally applied just to *physician* claims," he continued. "In

Advisory Committees Expand ACLA's Work For Lab Industry

DURING THE LAST TWO YEARS, THE SCOPE OF ACTIVITIES FOR ACLA has undergone considerable expansion. Each of these working groups is comprised of representatives from ACLA's member laboratories. Where appropriate, they use outside experts, such as legal and accounting. In some cases, advisory groups have produced information and publications for use by any laboratory interested in that material. A complete list of the information available can be obtained by calling 202-637-9466.

Standing Committees:

- Legislative & Regulatory Affairs Steering Committee
- Billing & Reimbursement
- Environmental & Occupational Health
- ESRD Issues
- Information Management Systems
- State Issues
- Legal

Ad Hoc Groups:

- CLIA Advisory Group
- Communications
- Pathologist/Scientist Advisory Group

fact, in the 1986 Medicare Catastrophic Coverage bill, Congress rejected a requirement that drug prescriptions include a diagnosis code. Congress thought it would be too burdensome. Of course, requiring a diagnosis code on a laboratory requisition raises precisely the same issues as requiring them on a prescription.

"How this was allowed to happen to laboratory orders is a mystery to me. As a physician, this is real interference in the practice of medicine. A patient is rarely a single diagnostic code. For this reason, the laboratory industry shares common ground with physicians on this issue. We hope improved communication between the laboratory industry and physicians can result in changes to this situation.

"Another busy advisory group involves Occupational and Environmental Health," said Dr. Sundwall. "Their activity was triggered by new government regulations that would have affected the disposal of certain types of laboratory waste. In addition, when Congress was considering legislation that would have affected the availability of certain types of pathogens, I testified in Senate hearings and we got the Center For Disease Control (CDC) to acknowledge that independent laboratories should not be regulated in this area. Without those changes, clinical laboratories could

have found themselves operating under restrictive and inappropriate regulations concerning the transportation of 'lethal pathogens.' "

Managed care is another industry concern to which ACLA is responding. "Managed care has created financial problems for laboratories," he said. "Some of our members have told me that, in their urgency to get managed care contracts, they negotiated prices which were unrealistic and did not yield what they expected. Pull-through business was not sufficient to offset the low rates of capitation."

Pointed Lessons

"Having learned some pointed lessons by the way of reduced revenues, there is now interest in improving the way laboratories contract for, and provide services to, managed care plans.

"This change in the concerns of ACLA's members is reflected in our different priorities. When I started here, the top legislative priority was direct billing. That is no longer true because of the rapid decline in fee-for-service business. Other priorities are now ahead of direct billing.

"Such priorities include working with pathology groups on a variety of issues. For example, we are supporting the CAP to get a new code for computer-assisted Pap smear technologies. This would be a generic CPT code, and not linked to specific technologies such as **NeoPath's** AutoPap or **Neuromedical System's** PapNet. These instruments do cost money, and there should be payment for the improved accuracy that they deliver."

In commenting on ACLA's activities, Dr. Sundwall is proud of the comprehensive nature of association's work. "Virtually everything that we have done applies to most clinical laboratories. Billing, reimbursement and environmental issues affect all laboratories."

Is ACLA actively seeking to expand membership? "Although we have not gone out and marketed ourselves, I would like to see additional new members," responded Dr. Sundwall. "**ARUP Laboratories** recently joined. Their relationship with hospital laboratories brings us valuable insight. Among laboratory associations we seem to have a fairly strong voice in Washington. Additional members would enhance our credibility.

"We have our annual meeting in February. Part of the meeting is open to the public. It is an opportunity to see the association in action. We are also making a point to participate in other association meetings, such as the **American Association of Clinical Chemistry** (AACC) and the **Clinical Laboratory Management Association** (CLMA). Recently I spoke with the **California Clinical Laboratory Association** about some type of relationship with ACLA."

Expanding Activities

"It is easy to see that ACLA's activities are expanding," he continued. "As the laboratory industry is transformed, it is critical for associations like ACLA to represent the laboratory industry's interests with government and healthcare industry decision makers."

Sundwall is correct on this point. The laboratory industry is vulnerable to unwitting legislative actions as well as new business practices instituted by managed care companies. Today's ACLA represents a wider range of laboratory interests and activities than in the past. Laboratory executives would be well served to learn more about how ACLA can assist their laboratory organization. **TDR**

(For further information, contact David Sundwall, M.D. at 202-637-9766.)

The Dark Index

Cytyc Corp. Raising $48 Million To Fund ThinPrep Sales Effort

CEO SUMMARY: Armed with FDA premarket approval, Cytyc must now overcome significant obstacles to introduce its ThinPrep Pap smear system into widespread clinical usage.

ANOTHER WELL-FINANCED competitor will soon enter the Pap smear marketplace. **Cytyc Corporation** is offering 3,000,000 shares to the public with the goal of raising $48.2 million.

Cytyc will use $25 million of the proceeds to initiate a nationwide sales blitz of its ThinPrep® Sample Preparation System. Another $10 million will fund an international sales effort. Cytyc's domestic sales program will kick into gear by the second quarter of 1997. The balance of the $48 million will be retained as working capital.

Founded in 1987, the company labored for nine years to achieve premarket approval by the **Food and Drug Administration**. That approval was granted on May 20, 1996, permitting Cytyc to market the ThinPrep system for use in Pap smear specimen preparation. This was followed on November 6, 1996 by the FDA's clearance of an expanded product label which, among other things, allows Cytyc to claim that "specimen quality using the ThinPrep System is significantly improved over that of the conventional Pap smear method."

During the past nine years, Cytyc generated an accumulated deficit of $43.2 million. It raised capital twice. The first was a private placement for $43.3 million. An initial public offering last year generated $50 million in net proceeds. Most of these funds came from venture capital sources.

Within the clinical laboratory industry, there is widespread difference of opinion about both the clinical effectiveness and economic viability of various new Pap smear technologies. Controversy over such issues means that Cytyc must introduce ThinPrep into a relatively hostile marketplace.

Within the clinical laboratory industry, there is widespread difference of opinion about both the clinical effectiveness and economic viability of various new Pap smear technologies.

Cytyc faces three major hurdles to successfully introduce the ThinPrep System. The first hurdle is acceptance by laboratories and physicians of the technology. The second hurdle is whether the marketplace will pay for the added cost of the ThinPrep procedure. Finally, the third hurdle is how third party payers will decide to reimburse for the procedure.

"From my perspective, the biggest challenge for Cytyc is the economics of Pap smear testing," stated one analyst who is familiar with Cytyc and competing firms. "At a time when managed care is driving costs out of the healthcare system, Cytyc wants to introduce a technology which is more expensive."

List price for ThinPrep Pap Tests will be $9.75 per test. This includes reagents, filters and other supplies. The ThinPrep 2000 Processor will list at $39,000 per processor. It is expected that these prices will be discounted significantly for high-volume users.

Commercial Lab Pricing

Major commercial labs commonly offer pricing of around $7 per Pap smear for high volume contracts. The three national laboratories, **Laboratory Corp. of America**, **SmithKline Beecham Clinical Laboratories** and **Quest Diagnostics**, each do about 5 million Pap smears annually. They act as price leaders in the specific regions where they have dominant market share.

Pap smears priced at $7 barely cover marginal costs. As reported earlier in THE DARK REPORT, all three major laboratories consider cytology to be a loss leader that is uneconomical. *(See TDR, April 8, 1996.)* They calculate that a price per Pap smear of around $15 is closer to the full cost of providing the test.

If $15 is the true cost to perform a Pap Smear test, then Cytyc's ThinPrep System would add at least $5 to the cost of the procedure, assuming a 50% discount to high-volume users. This means that major laboratories would need a reimbursement of at least $20 to recover full costs and utilize the ThinPrep technology.

"In my opinion," stated the analyst, "the critical success factor for Cytyc will be whether they can get third party payers to reimburse for ThinPrep at a level that allows laboratories to provide the service and recover their costs."

ThinPrep System Uses Monolayer Technology

Cytyc's ThinPrep® System is actually a new process for preparing a Pap smear specimen. The device used to collect cervical cells is rinsed in a vial instead of being smeared on a microscope slide.

The solution, which Cytyc calls PreservCyt, preserves virtually all of the patient's cell sample. The vial is shipped to a laboratory where Cytyc's ThinPrep 2000 Processor is used to prepare the actual specimen.

The processor begins by gently dispersing blood, mucus, non-diagnostic debris and large sheets of cells. As the specimen becomes homogenized, cells are caught against Cytyc's proprietary cell filter. It is an eight micron membrane which is specially designed to collect abnormal and cancerous cells. Cells collected by the filter are then transferred to a glass slide where they are deposited in a thin, uniform layer, stained and preserved.

Slides prepared this way are remarkably uniform. They consistently present 70,000 to 75,000 readable cells. This compares to a traditional Pap smear, where the number of readable cells can vary from 4,000 to 300,000. The ThinPrep 200 Processor can complete between 20 and 25 samples per hour.

Like traditional Pap smears, a Pap smear slide processed under the ThinPrep System is then read by a cytotechnologist or pathologist. Also, ThinPrep slides can be read by the automated systems offered by NeoPath (AutoPap 300) and Neuromedical Systems (PapNet).

All companies offering automated cytology technology share the common problem of convincing third party payers that they should reimburse for Pap smear tests utilizing such technology. That is probably one of the reasons that Cytyc and Neopath announced a joint study in November 1996. The study will evaluate how effectively each company's technology complements the other in improving the diagnostic accuracy of Pap smears prepared by ThinPrep, then evaluated by the AutoPap 300.

Timing Of Public Offering

Cytyc is making this public offering now for two reasons. First, its stock price is close to $25, which permits it to raise considerable funds without a major dilution of existing stockholders. These funds will be used to finance sales activities and for working capital.

Second, of the three million shares to be offered, one million shares are currently owned by venture capitalists. They expect to net about $25 million from their stock. This is their "reward" for early investments in the company. Of interest, however, is the fact that none of Cytyc's senior executives are selling stock in this offering.

Number Of Challenges

Cytyc faces a number of challenges to successfully introduce its ThinPrep System into clinical usage. It also has a direct competitor waiting in the wings. **Autocyte, Inc.** has been spun off from **Roche** and is moving forward with their version of monolayer technology.

With NeoPath and Neuromedical's extensive sales and marketing efforts already under way, Cytyc's sales team becomes one more group of sales reps who will be calling upon clinical laboratory executives to convince them of the benefits of automated Pap smear technology. Expect fierce competition as the marketing wars intensify throughout 1997. TDR

(For more information, contact Cytyc Corporation at 508-263-8000.)

Background of Cytyc's Management Team

Patrick J. Sullivan
President and CEO

*With Cytyc since 1991. Promoted to President in March 1994. Formerly with **Abbott Laboratories** and **McKinsey and Company.** Graduate of the United States Naval Academy and a Harvard M.B.A.*

Joseph W. Kelly
Chief Financial Officer

*Joined Cytyc in November 1995. A C.P.A., Kelly was Chairman and CEO of **Crop Genetics International**. He was also a Partner with **Deloitte, Haskins and Sells** (now **Deloitte & Touche**).*

Daniel J. Levangie
Vice President of Sales

*Levangie joined Cytyc in 1992. Formerly he was with **Abbott Laboratories**.*

Robert J. Silverman
Vice President of Marketing

*Came to Cytyc in October 1996. Formerly with **Pasteur-Marieux-Connaught** and **Abbott Laboratories**.*

David J. Zahniser, Ph.D.
Vice President, Scientific Affairs

*Dr. Zahniser started at Cytyc in 1989 as Scientific Director. Prior to that he was Associate Director of the Image Analysis Laboratory at **Tufts University Medical Center**.*

James Linder, M.D.
Medical Director

*Joined Cytyc in March 1996 as Medical Director. Dr. Linder is Associate Dean at the **University of Nebraska** College of Medicine.*

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Persistence can pay off. After years of struggle, **Epitope, Inc.** of Beaverton, Oregon received a big "shot in the arm" when the *Journal of the American Medical Association* (JAMA) reported this month on a clinical study involving Epitope's OraSure HIV test. The study involved 3,570 patients. It matched results of an HIV blood test against the OraSure saliva test. Orasure correctly identified 99.9% of the HIV positive specimens

MORE ON: Epitope, Inc...
Only one day after *JAMA's* publication, the **Whitman-Walker Clinic** in Washington, DC announced that it would completely replace traditional blood testing with OraSure on February 1, 1997. The news startled the local AIDS community, because Whitman-Walker treats two out of three people with AIDS in the Washington metropolitan area.

CALIF. PHLEBOTOMIST INDUCEMENT UPDATE

Although the state of California considers the placement of a phlebotomist in a physician's office to be an inducement under state law, laboratories in that state have been slow to stop the practice. THE DARK REPORT has learned that larger laboratories in the state have quietly begun to pull phlebotomists out of some doctor's offices. The motive is to save money. It is done discreetly, because each lab wants to prevent competitors from taking advantage of the change in service to the affected client.

Correction

On page 3 in the previous issue, dated January 6, 1997. David Beckwith, Ph.D. was incorrectly identified as "Richard Beckwith, Ph.D." THE DARK REPORT regrets any inconvenience this may have created.

Demonstrating again that information is a managed care essential, **Impath, Inc.** of New York City announced an agreement with privately held **Medical Registry Services, Inc.** The two companies intend to co-develop a software product that would enable oncologists and pathologists to identify and select the optimal treatment pathway for cancer patients.

One small niche laboratory earned positive recognition this month. **The Red Chip Review**, a prestigious research company specializing in small and micro cap companies, initiated coverage of **Laboratory Specialists of America** (LSA), located in Oklahoma City, Oklahoma. A SAMSA-certified lab, LSA specializes in drugs of abuse testing and has done several profitable acquisitions during the last 18 months.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, February 17, 1997

THE DARK REPORT

UPCOMING...

- *Contracting Laboratory Services With HMOs: Regional Differences Affect Reimbursement.*
- *Bringing Total Quality Management (TQM) Into The Laboratory To Cut Costs.*
- *Why On-Site Hospital Core Labs Are Falling Out Of Favor.*
- *Medicaid HMOs Multiply In Many States... Creating Problems For Laboratories.*