Part II of Our Exclusive Coverage **Pathology Lab Condos:** Secrets Promoters Want to Hide!

From the Desk of R. Lewis Dark...

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

<i>R. Lewis Dark:</i> "Actionable Intelligence" in Real Time	Page	1
Part II: Path Lab Condominiums As a Threat to Pathology	Page	2
LabCorp's Smith Speaks On Path Condominium Lab Trend	Page	4
Congress and the OIG: Speedy Action Ahead?	Page	6
Peeking into the Finances Of Pathogy Laboratory Condos	Page	8
Pathology Marketplace: Pathology Consultants See In-House AP Trend Unfolding	Page	13
AP Test Over-Utilization Will Be One Achilles' Heel	Page	14
Exposed: Who Created Path Lab Condominium Scheme	Page	16
Visit to a Path Lab Condo Complex: "You Are Not Welcome!"	Page	21

Restricted information, see page 2





"Actionable Intelligence" In Real Time

BEFORE YOU READ THIS ISSUE, I would like to make three observations. Each will help you get maximum value from the information contained herein about the trend of in-house anatomic pathology (AP) laboratories in specialist physician groups.

First, THE DARK REPORT'S coverage of this trend is unmatched by any other source in the lab industry. Not only are we first to identify the scope and scale of this trend—even as it is gathering momentum in the healthcare marketplace—but we are providing you with facts and analysis that are unavailable from any other single source. This intelligence gives you competitive advantage when crafting your lab's strategy to cope with this trend.

Second, THE DARK REPORT is giving you a front row seat. You are watching a major trend unfold in front of you, in real time. I hope you fully appreciate the business advantage this gives you and your laboratory. Armed with this knowledge, your laboratory has an opportunity to <u>respond to this trend</u> <u>proactively</u>. You can educate your specialist physician clients to the full range of risks, <u>before</u> they hear the siren calls of AP condo laboratory promoters (who are often willing to over-represent and under-disclose to make a sale).

Three, THE DARK REPORT'S coverage of this trend, requiring two expanded issues, contains a wealth of unpublished facts and sophisticated analysis that allows you to make your own determination about the impact of this trend on your laboratory. We define this as "<u>actionable intelligence</u>." It is intelligence that arrives <u>before</u> an event and allows you to make an intervention that <u>changes</u> the outcome in positive ways. Again, this is a value-added trait unique to THE DARK REPORT.

I am amazed at what our editor has produced—to give you a competitive edge. He's identified the major promoters behind this trend. He's obtained and published the financial projections used to persuade specialist physicians to invest in an AP lab. He's sharing 12-core prostate biopsy utilization data unavailable anywhere else. He's even managed to get a site visit and photos of an AP laboratory condominium complex. All of this required intense detective work and many hours of effort.

Put this actionable intelligence to good use. Contact your specialist physician clients. Let them read for themselves about this trend. Act decisively to preserve your role as a trusted provider of AP services in your town.

Part II: Path Condo Labs As A Threat to Pathology

In-house anatomic pathology laboratories enable specialist physicians to profit from AP

CEO SUMMARY: Specialist physician groups are targeting anatomic pathology (AP) as a source of ancillary service revenue. One national laboratory company already considers this trend to be a major threat to its AP business. Here is Part II of THE DARK REPORT'S coverage of this unfolding trend, including exclusive intelligence about the financial projections used by promoters to attract the investment dollars of specialty docs.

By Robert L. Michel

Specialist PHYSICIAN GROUPS are taking active steps to capture anatomic pathology (AP) revenues that result from specimens generated by their groups' patients.

Yet the anatomic pathology profession is only now awakening to this threat. To educate and alert pathologists and their group practice administrators to this trend, we are devoting this entire issue to the subject of how specialist physicians use various inhouse AP laboratory arrangements to capture AP revenues.

It is Part II of our coverage. Part I included information: 1) that defined this trend; 2) described the new phenomenon of "anatomic pathology laboratory condominium complexes"; 3)

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

presented the pros and cons facing specialist physician groups when they opt for an in-house AP laboratory within their existing clinic facilities versus an off-site pathology lab condominium arrangement; and 4) recent economic changes that now motivate greater numbers of urologists and gastroenterologists (GI) to take active steps to capture the AP revenues generated by their patients. (See TDR, July 19, 2004.)

In Part II, we offer exclusive intelligence for our clients and regular readers. We lift the veil of secrecy from the most troubling aspect of the trend by specialist physicians to bring AP revenues in-house: AP laboratory condominium complexes. You will learn who created this convoluted

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scheme, why it's attracted the investment dollars of many urology and GI groups, and how it was developed.

THE DARK REPORT will show you the actual financial spreadsheets and projections one AP lab condo promoter uses in marketing the concept. This analysis is balanced by a more accurate assessment of the financial opportunity when a specialist group does build its own AP laboratory.

We also have a family tree that shows how the AP lab condo scheme is branching out. Still a nascent phenomenon, AP lab condo complexes are mushrooming in the states of Florida and Texas. But we don't stop there! You will see photos of one such condo lab complex, along with what THE DARK REPORT learned during its surprise visit to this particular site.

First Public Revelations

Much of what you will read has, until publication of this issue of THE DARK REPORT, been unknown—even to some of the urology and gastroenterology groups which bought an AP laboratory condominium. We want you to understand all dimensions of this trend. It's knowledge you need so your pathology group practice can craft an offensive strategy to inform and educate your group's specialist physician clients before they approach your pathology practice with proposals to capture AP service revenue for themselves.

The legal and compliance issues triggered by an in-house AP laboratory are significant. On pages 6-7, you will read what Chief Legal Officer Brad Smith of Laboratory Corporation of America has to say about the compliance concerns surrounding both the general concept of in-house AP labs and the unique case of the AP laboratory condominium. LabCorp and Smith have first-hand knowledge of how the federal healthcare compliance and enforcement functions operate. He is convinced that most specialty physicians greatly under-estimate the compliance risk attached to their anatomic pathology ancillary service venture.

OIG and Senator Grassley

Early evidence that Smith's convictions may be on target are the public statements of the **Office of the Investigator General** (OIG) and Senator Charles Grassley (D-Iowa). Both the OIG and Senator Grassley have already publically declared that they are aware of the heightened interest by specialist groups to create in-house AP laboratories. Senator Grassley is calling for an OIG investigation and report. (See pages 4-5.)

Over-utilization and medically unnecessary testing are just two of the compliance concerns linked to specialist groups building an in-house AP laboratory. Those concerns are warranted, since some AP lab condo promoters give urologists financial projections that base in-house AP lab revenues on 100% utilization of 12-core prostate biopsies.

In this issue, THE DARK REPORT will blow the lid off that scheme. On pages 14-15, we present data from a national AP billing service. You will read about the actual data on coresper-prostate specimen currently ordered by physicians practicing in 21 states, and representing as much as 3% of all prostate biopsies performed nationally each year. Make your own guess at what the 12-core prostate biopsy rate is for this population, then check your answer with our story.

Finally, to provide visual context to the AP lab condominium complex scheme, an agent of THE DARK REPORT visited one such site in San Antonio, Texas. On pages 21-22, you will learn about that visit and see pictures of this AP lab condo complex. TDR *Contact Robert Michel at 512-264-7013*.

LabCorp's Smith Speaks On New Pathology Trend

In-house anatomic pathology laboratories may prove a compliance trap for specialist docs

CEO SUMMARY: During the past decade, Laboratory Corporation of America's Brad Smith faced the spear point of evolving Medicare/Medicaid compliance initiatives which changed so many laboratory industry business practices. Smith believes that business models for in-house anatomic pathology labs now being offered to specialist physician groups fail to meet important Medicare compliance criteria.

E FFORTS BY SPECIALIST PHYSICIAN GROUPS to make anatomic pathology an in-house ancillary service can trigger disruptive consequences in several ways. That's the assessment at **Laboratory Corporation of America**, the nation's second largest lab company, based in Burlington, North Carolina.

"This is a trend which is likely to be counterproductive to all stakeholders in healthcare, not just pathology," declared Bradford T. Smith, Executive Vice President and Chief Legal Officer at LabCorp. "It has the potential to negatively affect patient care, to trigger a negative perception of all pathology labs, when federal healthcare regulators take action to stop these abusive practices, and to disrupt longstanding relationships between anatomic pathologists and the physicians who refer specimens to them."

Major Threat To Pathology

Smith singled out the pathology condominium laboratory scheme for specific criticism. "We view this as a major threat to the anatomic pathology business—not just at LabCorp but throughout the profession," he said. "It is a clear violation of the intent that existing compliance laws were designed to prevent. Pathology condominium labs are probably the most potentially abusive scheme to hit healthcare in fifteen years.

"Specialist physician groups that buy into this concept without good legal advice are venturing into troublesome territory," explained Smith. "We've done extensive legal research and we think the pathology laboratory condominium scheme unquestionably violates the intent of the law.

"Among other legal concerns, the specialist group is making a relatively minor investment that has no risk promoters tell them they can get their investment back in just a few months, because they control an existing volume of specimens from their own practice which guarantees their pathology laboratory condominium is profitable," noted Smith.

"Next, does the anatomic pathology (AP) lab owned by the specialist group really meet the in-office ancil-

5 / THE DARK REPORT / August 9, 2004

lary service exception, when it is frequently located in another city, and even in another state?" Smith asked. "I don't think federal health program investigators will agree that physicians from the specialty group are actually supervising their AP lab's functions across that physical distance."

"Most specialist physicians do not have the same level of awareness...about the compliance issues in lab testing which are closely watched by federal health program regulators."

"Specialist groups, in their attempts to capture AP revenues, are starting down a Medicare Fraud and Abuse road already traveled by the laboratory industry in the last decade," he continued. "That was when the compliance concepts of over-utilization and medically unnecessary laboratory tests were viewed by regulators as generating false claims to the Medicare/Medicaid programs.

"If the specialist physician orders a test on his/her patient, to be performed by the anatomic pathology laboratory owned by his/her group, and OIG investigators later deem such tests to be medically unnecessary, then the specialist group has generated false claims and will find itself in violation of the Medicare Fraud and Abuse law," observed Smith.

Compliance Crossover

"The evolution of what constitutes acceptable behavior in Medicare and Medicaid compliance law is an important point," he continued. "Compliance theories cross over from one area of healthcare to another. Providers often fail to notice this development and continue practices now considered, by the evolving body of compliance law, to violate Medicare statutes. "Months or years later, federal investigators investigate the other health specialities," noted Smith. "They often apply, by analogy, precedents (developed in another area of healthcare) to establish kickback or false claims violations.

"In the last decade, the new compliance concept was that laboratories were inducing physicians, through marketing techniques, to order medically unnecessary tests," he said. "It's not a big leap for federal investigators to apply that same concept to pathology lab condominium schemes and even to the anatomic pathology laboratories newly-created within a specialist group's main clinic facility.

"If federal investigators can document a change in utilization and test ordering patterns before and after the in-house AP lab came into operation," predicted Smith, "then the group practice may find itself facing allegations of false claims and other violations."

Impact On Patient Care

Smith also believes that many AP lab arrangements have the potential to affect patient care. "No longer will the choice of an anatomic pathology provider be made on the basis of quality services and specialized clinical expertise," he observed. "Rather, these decisions will be driven to use a source chosen by a doctor who profits from the referral of the AP specimen. This situation is one reason why Congress enacted the Stark Amendments."

Smith has identified some major compliance land mines for this growing trend of in-house AP laboratories at specialist physician groups. Based on his considerable experience in the field of laboratory compliance, he has a high degree of confidence that these arrangements will be closely-scrutinized by federal health program investigators. The question is how quickly such scrutiny occurs. **TDE** *Contact Brad Smith at 336-584-5171*.

Of Congress and the OIG: Speedy Action Ahead?

Rapidly accelerating trend could boomerang and bring the wrath of OIG investigators

CEO SUMMARY: During the short life of AP laboratory condominium complexes, they have attracted the interest of both an influential Senator and the Office of the Inspector General (OIG). Last month, Senator Charles E. Grassley sent a letter to the OIG requesting that it investigate the AP lab condo scheme and report its findings to him. Earlier this year, a national AP company requested an opinion from the OIG on AP ventures.

E VEN AS THE NUMBER of pathology condominium laboratory complexes mushrooms in states like Florida and Texas, they are attracting the attention of Congress and the **Office of the Inspector General** (OIG).

On June 10, 2004, Senator Charles E. Grassley (R-Iowa) sent a letter to the OIG specifically requesting that the government agency investigate the growing number of "anti-competitive joint ventures" between "some providers of pathology services and treating physicians." In his letter, Grassley notes that the arrangements allow participating physicians to "expand into the pathology market with little investment of resources and and share revenues from their referrals for pathology services."

Grassley notes that such joint venture arrangements can potentially violate antikickback laws, the Stark self-referral law, and the OIG's recent Special Advisory Bulletin on contractual joint ventures. He further observes that such pathology service joint ventures can encourage overutilization and a decline in the quality of patient care, both contrary to the goals of the Medicare program. Grassley's letter was sent about the same time that an official of the OIG made a public statement acknowledging that the agency was aware of these pathology joint ventures and was looking into the situation. That statement is considered to be a public notice that the OIG wanted to alert the healthcare marketplace that it knows about this trend and will have more to say at a future date.

OIG Opinion Requested

The OIG's attention has also been drawn to the AP laboratory condo complex concept because it received a letter requesting an opinion on a business arrangement that is similar to the existing AP lab condo complexes operating today in Florida and Texas.

The opinion was requested by **CBLPath, Inc.** in January 2004. THE DARK REPORT contacted CBLPath and spoke to its attorney. "During the past year, specialist physician groups were engaging our sales reps in conversations about they could develop an anatomic pathology ancillary service joint venture or collaboration," stated Thomas Bartrum, Attorney at **Baker Donelson** in Nashville, Tennessee.

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United States Senate COMMITTEE ON FINANCE WASHINGTON, DC 20510-620

June 10, 2004

VIA FACSIMILE & USPS MAIL

Acting Principle Deputy Inspector General Department of Health and Human Services Ms. Dara Corrigan 330 Independence Ave, SW Washington, DC 20201

Dear Ms. Corrigan:

It has come to my attention that there is a troubling trend in the filed of pathology It has come to my attention that there is a troubling trend in the filed of pathology of quality pathology care, and undermine the goals of forderal fraud and abuse prevention measures. It was reported to me that some providers of pathology services and treating hysicians have been entering into an atticcompetitive joint ventures that raise concerns under fraud and abuse laws. These joint ventures that raise concerns physicians and allow referring hysicians to share in the revenues carmed by laboratories on their pathology referrals.

on mer pathology referrats. Based on my review of this issue it is apparent that the arrangements in question tary in form and structure, but all have certain common elements. In most cases, an existing laborators to expand into the pathology market with little investment of referring physicians to across and into the pathology market with little investment of resources and share revenues from their referrals for pathology services. These joint well-being and quality standards of the Medicare program, and create serious questions Control the anti-kickback law, the Stark self-referral law, and the Office of Inspector under is recent? Special Advisory Bulletin on contractual joint ventures.

In essence, these practices would appear to encourage over-utilization of health care services, leading to higher Medicatteching two packets of marketing materials imited resources. Accordingly, 1 am attaching two packets of marketing materials promoting these types of arrangements. I request that you examine this matter and get back to me

Thank you in advance for your assistance on this matter. Should you have any questions regarding this letter, please do not hesitate to contact Emilia DiSanto or Michelle Anderson at (202) 224.4515.

muck Ara Charles E. Grassley Chairman

"CPBPath looked at developing a business model to serve this growing interest by our physician clients," he explained. "It was immediately clear that various laboratory compliance requirements would come into play. In our analysis of the legal issues, we believed that a letter of opinion to the OIG would be answered in either of two ways.

"First, the OIG could issue a favorable opinion for our specific joint venture (JV) structure," said Bartrum. "Obviously, this provides CBLPath with reassurance before moving forward to implement such JVs. But if the opinion was negative, to the degree such a joint venture was not doable, then we would understand the legal consequences of developing such a joint venture. In this event, we would also have an OIG opinion to show specialist physicians, so they could understand

Grassley Writes OIG on Path Lab Condos

HERE IS THE LETTER SENT by Senator Charles E. Grassley (R-lowa) to the Office of the Inspector General (OIG) on June 10, 2004. The letter expresses his concerns about the impact of specialist physicians acquiring in-house anatomic pathology laboratories.

In the letter, Senator Grasslev defines the problem as "some providers of pathology services and treating physicians have been entering into anti-competitive joint ventures that raise concerns under fraud and abuse laws." He requests that the Acting Principal Deputy Inspector General "examine this matter" and report back to him.

for themselves how and why the OIG objected to such opinions."

A CBLPath subsidiary would establish a number of AP labs in a centralized location. It would provide management services those labs, including office rental, equipment rental and employee leasing. CBLPath would provide technical services, the specialist physicians would provide professional AP services. AP labs would be located in or near the specialist groups' city. To create financial risk for the specialist group, there would be a fixed fee paid, along with charges that did vary with specimen volume.

"Since submitting our letter in January, we have twice provided supplementary information to the OIG," Bartrum said. "That indicates to us the type of compliance concerns they are evaluating. However, we do not know when the OIG opinion will be issued." TDR Contact Tom Bartrum at 615-726-5720.

Peeking Into Finances Of Pathology Lab Condos

"Bare bones" revenue and expense projections are used to sway specialist physicians

CEO SUMMARY: In the possession of THE DARK REPORT is a copy of revenue and expense projections shown by a pathology condo laboratory complex promoter to prospective urology groups. They project that even smaller urology groups can realize worthwhile income if they invest in a pathology condo lab and operate it successfully. This is validated by other financial projections done by a veteran laboratory executive.

HY DO SPECIALIST PHYSICIANS opt for a pathology laboratory condominium as the preferred way to bring pathology services into their group practice?

To understand the motives and incentives which make this pathology option attractive to specialist physicians, it is necessary to understand the financial opportunities—from the doctors' perspective. Companies which package and operate pathology laboratory condominiums on behalf of specialist physicians use some controversial assumptions to create an attractive financial picture.

Analyzing Their Projections Recently THE DARK REPORT obtained copies of revenue projections used by a pathology lab condo company based in Florida to show prospective urology and gastroenterology (GI) groups how the scheme works. (*See sidebar on pages 11-12.*) THE DARK REPORT is publishing the pathology profession's first look at how the pathology lab condo organizers present their scheme to specialist physicians.

These projections show revenue, expense, and net income projections to

be realized from a pathology laboratory condo linked to a small, a mid-sized, or a large urology practice. Joe Plandowski, President of the **Lakewood Consulting Group**, based in Lake Forest Illinois, is tracking the pathology laboratory condominium phenomenon. When provided with the pathology lab condo company's revenue and profit projections, Plandowski analyzed this information and developed several useful insights and conclusions.

"My first impression was that this is a most unprofessional presentation," observed Plandowski. "It is an Excel spreadsheet printout and the projections are poorly presented, contain inaccuracies, and fail to properly account for the expected case mix. Not only do these revenue/expense projections lack sophistication, but they don't paint a full and accurate picture of the true costs to operate a pathology laboratory.

"However, even if these projections are flawed in certain aspects, they do capture one essential fact: a modestsized pathology laboratory can deliver worthwhile net income to whomever owns it," explained Plandowski. "As you can see from the projections themselves, the pathology lab condo developers are saying that any small urology group can net \$66,616 per year from their lab, based on 250 cases per year.

"For mid-sized urology groups generating 250 cases per year, net income is projected to be \$188,511," he said. "At 1,000 cases per year, a large urology practice is projected to earn annual net income of \$428,466.

Recasting The Projections

"Having seen these numbers," added Plandowski, "I did my own calculations. I modeled a urology example and a gastroenterology example. Included in my model are very specific assumptions that are lacking in the pathology lab condo projections. Not surprisingly, my urology numbers came out different than theirs." (See sidebar, next page.)

"In my GI model, I had two assumptions of the average number of biopsies per case," he noted. "At 8,000 cases per year, a GI group could expect to see a profit contribution of either \$560,000 or \$850,000, assuming 1.0 and 1.5 biopsies per case, respectively.

"My urology model assumes 1,000 cases per year," continued Plandowski. "The urology group could generate a profit contribution of either \$507,000 or \$1,074,000, based on 6-core biopsies and 12-core biopsies, respectively. I would caution anyone trying to compare my financial model with the one believed to have come from the Florida pathology lab condo company. It lacks the necessary assumptions required to have a useful and reliable revenue and expense model."

There are several aspects of the pathology condominium business scheme which disturbed Plandowski. "One concern is this promoter's reliance on a 12-core prostate biopsy as the basis for revenue projections," he said. "Obviously this increased the net collected revenue per prostate biopsy case. But there remains significant difference of opinion in the clinical community as to whether or not a blanket use of a 12core procedure is clinically useful.

"I'll avoid the clinical question for a moment and ask a practical business question: what happens if Medicare, upon seeing a rapid increase in the number of claims for 12-core biopsies, makes an arbitrary decision to reduce its claims exposure? It can do that by either writing strict rules for eligibility to file a 12-core biopsy claim, or by simply reducing the rate of reimbursement it pays for these procedures," conjectured Plandowski.

"Now take this one step further. If Medicare takes effective steps to reduce either utilization or reimbursement, it is likely private payers will follow with similar actions," he noted. "The net effect is destructive to the entire profession of anatomic pathology, not just the owners of these pathology lab condos. A significant portion of the revenue relied upon in the local pathology group practive to provide a full mix of anatomic pathology services shrivels up."

Reward And Risk

THE DARK REPORT observes that pathologists should recognize one compelling fact from these financial models: any specialist physician group with sufficient specimen volume can make plenty of money from an in-house anatomic pathology laboratory. However, that may not compensate the AP lab owners for increased compliance risk, additional malpractice exposure, and other challenges familiar to pathologists.

"Pathologists, after studying these numbers, should understand that the economics of healthcare are changing," observed Plandowski. "The old business models of pathology are becoming increasingly outmoded."

Contact Joe Plandowski at 847-295-8805.

Lab Exec Evaluates Profit Potential Of In-House Pathology Laboratory For Urology & GI Groups

Two revenue analyses are presented, one for gastroenterology and one for urology. Each was prepared by Joe Plandowski, President of Lakewood Consulting Group,

Gastroenter	Gastroenterologist' In-Office Pathology Laboratory — Endoscopy Center w/1.0 to 1.5 Biopsies per Case										
	Av	erage of 1 Biop	sy/Case	Ave	rage of 1.5 Bio	psies/Case					
	3rd Party	Medicare	Total	<u>3rd Party</u>	Medicare	<u>Total</u>					
Cases/Year	4,000	4,000	8,000	4,000	4,000	8,000					
Biopsies: Slides/Year Net Biopsy Fee Biopsy Revenue	4,000 <u>\$125</u> \$500,000	4,000 <u>\$100</u> \$400,000	8,000 <u>na</u> \$900,000	6,000 <u>\$125</u> \$750,000	6,000 <u>\$100</u> \$600,000	12,000 <u>na</u> \$1,350,000					
H. Pylori: Tests/Year Net Test Fee H. Pylori Revenue	Tests/Year 1,000 1,000 2,000 1,000 2,000 Net Test Fee \$90 \$70 na \$90 \$70 na H. Pylori Revenue \$90,000 \$70,000 \$160,000 \$90,000 \$70,000 \$160,000										
AB-PAS Stain: Tests/Year Net Test Fee IHC Revenue Total Revenues	400 <u>\$65</u> \$26,000 \$616,000	400 <u>\$65</u> \$26,000 \$866,000	400 <u>\$50</u> \$20,000 \$690,000	800 <u>na</u> \$46,000 \$1,556,000							
Total Revenues \$616,000 \$490,000 \$1,106,000 \$866,000 \$690,000 \$1,556,000 Expenses: Lab Labor \$120,000 \$170,000 \$250,000 \$170,000 \$170,000 \$10,000 \$10,000 \$1120,000 \$1120,000 \$1120,000 \$1120,000 \$1120,000 \$110,000 \$110,000 \$110,000 \$110,000 \$60,000 \$110,000 \$60,000											
Contribution			\$560,000			\$850,000					
Notes: * Numbers are rounded for ease * 3rd Party Biopsy and other tes	in understanding the fir t fees shown are net co	llected fees.	ple, en	oor includes 2 FTEs in the 1.0-bio compassing. Lab Assistant, Med It reporting activities.	Ťećh and Histotech po	TEs in the 1.5-biopsy exam- sitions covering order entry					

* Medicare Biopsy, H. pylori and AB-PAS fees based on global CPT Codes 88305, 88312 and 88313, respectively.

Biopsies per case are low compared to Urology practices because Gastroenterologists can directly view the stomach, esophagus and colon through a variety of endoscopy devices.

H. pylori (Helicobacter pylori) is definitive for ulcers which can be treated with antibiotics.

AB-PAS (Alcian Blue Periodic Acid Schiff) detects intestinal or goblet cell metaplasia (Barrett's esophagus).

* Pathologist is an employee working half-time in the 1.0-biopsy example and full-time in the 1.5-biopsy example.

Billing services are provided by an outside company performing satisfactory billing for other pathology groups.

Rent includes cost of modifying an office to accommodate a pathology laboratory.

Equipment Depreciation is straight-line over 5 years on a \$200,000 investment in the 1.0-biopsy example and on a \$300,000 investment in the 1.5-biopsy example.

	Urologists' In-Offi	ce Pathology	Laboratory — (Comparison of 6- versus	12-Biopsies	
	Histo	rical (6-Biopsie	es/Case)	New Th	ninking (12-Biop	sies/Case)
Cases/Year	<u>3rd Party</u> 550	Medicare 450	<u>Total</u> 1,000	<u>3rd Party</u> 550	Medicare 450	<u>Total</u> 1,000
Biopsies: Slides/Year Net Biopsy Fee Biopsy Revenue	3,300 <u>\$125</u> \$412,500	2,700 <u>\$100</u> \$270,000	6,000 <u>na</u> \$682,500	6,600 <u>\$125</u> \$825,000	5,400 <u>\$100</u> \$540,000	12,000 <u>na</u> \$1,365,000
Cytospins: Slides/Year Net Cytospin Fee Cytospin Revenue	3,300 <u>\$65</u> \$214,500	2,700 <u>\$50</u> \$135,000	6,000 <u>na</u> \$349,500	6,600 <u>\$65</u> \$429,000	5,400 <u>\$50</u> \$270,000	12,000 <u>na</u> \$699,000
Net Revenues	\$627,000	\$405,000	\$1,032,000	\$1,254,000	\$810,000	\$2,064,000
Expenses: Lab Labor Pathologist Billing Supplies Rent/Utilities Equipment Depr. Other			\$115,000 \$125,000 \$75,000 \$40,000 \$40,000 \$40,000 \$50,000			\$230,000 \$250,000 \$160,000 \$150,000 \$60,000 \$60,000 \$80,000
Total Expenses			\$525,000			\$990,000
Contribution			\$507,000			\$1,074,000
Notes:			* lah lu	nhor includes 2 FTFs in the 6-bio	osv example and 4 F	TFs in the 12-hionsy exam

⁷ Numbers are rounded for ease in understanding the financials.

* 3rd Party Biopsy and Cytospin fees shown are net collected fees.

* Medicaré Biopsy and Cytospin fees are based on global CPT Codes 88305 and 88108, respectively

12'biopsies of the prostate are believed to be about 20% more effective than 6-biopsies in disease detection.

Biopsies placed in non-formalin fixative to accommodate Cytospins.

* The Cytospin procedure has been shown to reduce equivocal or inconclusive results by about 50% and increase diagnostic result yields by about 3%.

Lab Labor includes 2 FTEs in the 6-biopsy example and 4 FTEs in the 12-biopsy exam-ple. They range from Lab Assistant to Medical Technologist and cover order entry to result reporting.

Pathologist is an employee working half-time in the 6-biopsy example and full-time in the 12-biopsy example.

Billing services are provided by an outside company performing satisfactory billing for other pathology groups.

Rent includes cost of modifying an office to accommodate a pathology laboratory.

Equipment Depreciation is straight-line over 5 years on a \$200,000 investment in the 6-biopsy example and on a \$300,000 investment in the 12-biopsy example.

12-Month Proforma

0.53

90%

\$236.448

(23.845)

Revenue

Billinas

Adjustments

of Support Staff

Collections % Billings

Income Statement Projection

	G	eneri	ic S	Smal	l Pra	ctice
--	---	-------	------	------	-------	-------

Proforma Assumptions		Revenue Table		Specimen			
			Procedures	(CPT) Count	Medicare Rate	Billings	Collections
Cases Per week	4.8						
Number of Cases per year	250	Gross Billings					
Average # of Cores per Case	12	Level 1 - CPT #88300	-	-	\$13.39	-	-
Urine for Cytology per workday	0.5	Level 2 - CPT #88302	2	2	\$29.06	\$65	\$59
		Level 3 - CPT #88304	1	1	\$38.12	\$43	\$39
Payor Mix		Level 4 - CPT #88305	203	2,430	\$86.53	\$210,268	\$189,241
Medicare %	54.0%.	Level 5 - CPT #88307	7	7	\$148.66	\$1,003	\$903
Commercial % Eligible to send	36.0%	Level 6 - CPT #88309	-	-	-	-	
% not Eligible to send	10.0%	Immunoperoxidase #88342	21	255	\$76.99	\$19,644	\$17,880
Total (must equal 100%)	100.0%	Cytology - CPT #88108	113	113	\$48.22	\$5,425	\$4,882
		Total	346	2,808		\$236,448	\$212,804
Avg Commercial - as % of Medicare	100%	12-Month	Proform	a (Generic Mic	l Sized	Practice

Pathology Condo Laboratory Promoter's Financial Projections

12-Month Proforma	Gene	Generic Mid Sized Practice								
Proforma Assumptions		Revenue Table		Specimen						
			Procedures	(CPT) Count	Medicare Rate	Billings	Collections			
Cases Per week	9.6									
Number of Cases per year	500	Gross Billings								
Average # of Cores per Case	12	Level 1 - CPT #88300	_	_	\$13.39	_	-			
Urine for Cytology per workday	8	Level 2 - CPT #88302	5	5	\$29.06	\$131	\$118			
		Level 3 - CPT #88304	2	2	\$38.12	\$86	\$77			
Payor Mix		Level 4 - CPT #88305	405	4,860	\$86.53	\$420,536	\$378,482			
Medicare %	54.0%.	Level 5 - CPT #88307	14	14	\$148.66	\$2,007	\$1,806			
Commercial % Eligible to send	36.0%	Level 6 - CPT #88309	-	-	-	-				
% not Eligible to send	10.0%	Immunoperoxidase #88342	43	510	\$76.99	\$39,288	\$35,359			
Total (must equal 100%)	100.0%	Cytology - CPT #88108	450	450	\$48.22	\$21,699	\$19,529			
		Total	919	5,841	\$483,747	\$435,371	70,718			
	1000/									

These three spreadsheets are reproductions of documents given to a urology group by one of the pathology condominium laboratory organizers, most likely UroPath, LLC. Each was on a letter-size sheet of paper, obviously printed from an Excel spreadsheet. There was no company name, no date, no other information but what you see here. Apparently, this is the quality of information used by specialist physician groups to make the investment decision to launch a pathology condo laboratory.

Cash Collections	\$212,804	100.0%
Operating Expenses		
Payroll	31,907	15.0%
Payroll taxes and benefits	7,977	3.7%
Lab Supplies	10,640	5.0%
Office and Other Supplies	426	2.0%
Waste Disposal	2,400	1.1%
Rent/Lease - buildings	10,200	4.8%
Equipment Depreciation Expense	15,600	7.3%
Legal and Other Professional	2,000	0.9%
Insurance - General Liability	1,500	0.7%
Telephone & Telecommunications	1,200	0.6%
Postage & Freight	3,405	1.6%
Books, Dues & Subscriptions	2,000	0.9%
Licenses & Permits	1,500	0.7%
Physician - Contract Labor	39,909	18.5%
other operating expenses	1,125	0.5%
Total Operating Expenses	131,188	61.6%
Management Expenses	15,000	
Net Income/(Loss)	\$66,616	31.3%
Expenses per code - pathologist	\$14.00	
Expenses per code - laboratory	\$38.07	

Observations About the Path Condo Lab **Financial Projections**

These financial projections cover three business cases: a small urology group, mid-sized urology group, and a large uro ogy group. They are not sophisticated do

			010
Avg Commercial - as % of Medicard	e 100%	Total	919
Avg commercial - as 70 or medical	5 10070		12-Month Proforma
# of Support Staff	1.11		
Collections % Billings	90%		Proforma Assumptions
Income Statement Projection			Cases Per week
Revenue			Number of Cases per year
Billings	\$483,746		Average # of Cores per Case
Adjustments	(48,375)		Urine for Cytology per workday
Cash Collections	\$435,372	100.0%	
			Payor Mix
Operating Expenses			Medicare %
Payroll	68,370	15.2%	Commercial % Eligible to send
Payroll taxes and benefits	16,592	3.8%	% not Eligible to send
Lab Supplies	21,769	5.0%	Total (must equal 100%)
Office and Other Supplies	871	2.0%	
Waste Disposal	2,400	6.0%	Avg Commercial - as % of Medicar
Rent/Lease - buildings	10,200	2.3%	
Equipment Depreciation Expense	15,600	3.6%	# of Support Staff
Legal and Other Professional	2,000	0.5%	Collections % Billings
Insurance - General Liability	1,500	0.3%	
Telephone & Telecommunications	1,200	0.3%	Income Statement Projection
Postage & Freight	6,966	1.6%	Revenue
Books, Dues & Subscriptions	2,000	0.5%	Billings
Licenses & Permits	1,500	0.3%	Adjustments
Physician - Contract Labor	81,768	18.8%	Cash Collections
other operating expenses	1,125	0.3%	
Total Operating Expenses	231,860	53.3%	Operating Expenses
			Payroll
Management Expenses	15,000		Payroll taxes and benefits
			Lab Supplies
Net Income/(Loss)	\$188,511	43.3%	Office and Other Supplies
Expenses per code - pathologist	\$14.00		Waste Disposal
Expenses per code - laboratory	\$28.27		Rent/Lease - buildings
			Equipment Depreciation Expense
			Legal and Other Professional
us flaws, such as colum	n totals w	nich	Insurance - General Liability
bo nuwo, both us tolon	in ioiuis wi	IICH	Tolophono & Tolopommunicationo

uments and close inspection reveals nun don't add up. One lab expert who reviewed these said "This is just plain sloppy work!" He also observed that many categories, such as waste disposal, rent, depreciation and telephone expense, seemed to be unaffected by volume. This illustrates that these financial projections are overly-simple and don't closely reflect the real operating experience. Further, there doesn't seem to be much revenue to the management company, raising the question of where else they may earn profit.

Proforma Assumptions		Revenue Table		Specimen			
· · · · · ·			Procedures	(CPT) Count	Medicare Rate	Billings	Collections
Cases Per week	19.2						
Number of Cases per year	1,000	Gross Billings					
Average # of Cores per Case	12	Level 1 - CPT #88300	-	-	\$13.39	-	-
Urine for Cytology per workday	3.5	Level 2 - CPT #88302	9	9	\$29.06	\$262	\$235
, , , ,		Level 3 - CPT #88304	5	5	\$38.12	\$172	\$154
Payor Mix		Level 4 - CPT #88305	810	9,720	\$86.53	\$841,072	\$756,964
Medicare %	54.0%	Level 5 - CPT #88307	27	27	\$148.66	\$4,014	\$3,612
Commercial % Eligible to send	36.0%	Level 6 - CPT #88309	-	-	-	-	. ,
% not Eligible to send	10.0%	Immunoperoxidase #88342	85	1,021	\$76.99	\$78,576	\$70,718
Total (must equal 100%)	100.0%	Cytology - CPT #88108	810	810	\$48.22	\$39.058	\$35,152
		Total	1,746	11,591	\$963,153	\$866,837	70,718
Avg Commercial - as % of Medicare	100%						
# of Support Staff	2.2						
Collections % Billings	90%						
.							
Income Statement Projection							
Revenue							
Billings	\$963,153						
Adjustments	(96,315)						
Cash Collections	\$866,837	100.0%					
Operating Expenses							
Payroll	131,717	15.2%					
Payroll taxes and benefits	32,929	3.8%					
Lab Supplies	43,342	5.0%					
Office and Other Supplies	1,734	0.2%					
Waste Disposal	2,400	0.3%					
Rent/Lease - buildings	10.200	1.2%					
Equipment Depreciation Expense	15,600	1.8%					
Legal and Other Professional	2,000	0.2%					
Insurance - General Liability	1,500	0.2%					
Telephone & Telecommunications	1,200	0.1%					
Postage & Freight	13,869	1.6%					
Books, Dues & Subscriptions	2,000	0.2%					
Licenses & Permits	1,500	0.2%					
Physician - Contract Labor	162.275	18.7%					
other operating expenses	1.125	0.1%					
Total Operating Expenses	423,392	48.8%					
Management Expenses	15,000						
Net Income/(Loss)	\$428,446	49.4%					
Expenses per code - pathologist	\$14.00						
Expenses per code - laboratory	\$23.82						

Generic Large Practice

Pathology Marketplace

Pathology Consultants See In-House AP Trend Unfolding

OCAL PATHOLOGY GROUP PRACTICES are themselves the "canary in the coal mine" to provide early warning about the exploding interest of specialist physicians at capturing the anatomic pathology (AP) revenues generated by their patients.

THE DARK REPORT interviewed three consultants, each of whom serves multiple pathology groups. Each reported that client pathology groups are in discussions with specialist physician clients about various ways the specialist groups might capture the AP revenues which result from test referrals for their patients.

"This is definitely happening to my clients in several regions," stated Laurence J. Peterson, President of **Torrey Consulting Group** of El Paso, Texas. "During the past 18 months, I've seen multiple instances of a urology or gastroenterology (GI) group approaching their local pathologists to explore some form of collaboration.

"Sometimes they have asked how to develop a relationship where they build their own laboratory, but have the local pathology group provide the professional service," continued Peterson. "This allows them to bill the technical component, but preserves their professional relationship with the local pathologists."

Prior to his retirement as a consultant last December, Dennis Padget, of **DLPadget Enterprises, Inc.**, a Simpsonville, Kentucky-based publisher of business practice guides for pathologists, saw a similar increase in such discussions. "It's that longstanding—but now growing—interest in lab services as a significant secondary revenue stream for specialists," he observed.

"These discussions raise two questions that implicate the status and stature of pathologists," Padget said. "First, are pathologists willing to give up their hardfought status as medical service 'retailers' dealing directly with the public by returning to the days when they were mainly 'wholesalers,' as happens with account-bill arrangements? Second, are pathologists willing to let the profession devolve from its stature as a primary medical specialty to one that's subordinate, as happens when specialists own their own real or faux-e.g., 'salon' or 'condo'-histology labs? The pathology profession will struggle to find the right answers to these questions."

Specialists Initiate Talks

"Pathology groups I work with in the Midwest, California, and Texas have been approached by their specialist clients over the past year," stated Mick Raich of Palmyra, Michigan-based Vachette Pathology. "We see a variety of proposals, but the net effect of each is less money for the pathologists.

"Nothing has yet developed from these proposals," he added. "But loss of revenue from such physicians is becoming a number one concern for a number of my pathology clients." **TDR** *Contact Larry Peterson at 915-833-*2294, Dennis Padget at 502-722-8873, and Mick Raich at 517-403-0763.

AP Test Over-Utilization Will Be One Achilles' Heel

12-core prostate biopsies may quickly attract attention of federal investigators

CEO SUMMARY: Over-utilization is likely to be a prime concern when federal healthcare enforcers eventually investigate in-house anatomic pathology laboratories owned by specialist physicians. Some in-house pathology lab condo promoters are basing financial performance on 100% utilization of 12core prostate biopsies. That significantly exceeds current clinical practices, as the numbers below demonstrate.

VER-UTILIZATION WILL BE one major Achilles' Heel in the ability of in-house anatomic pathology laboratories operated by specialist physician groups to fully meet Medicare and Medicaid compliance requirements.

This is the first observation made when experts well-versed in anatomic pathology (AP) lab compliance look at documents and projections that support various in-house AP lab schemes. It is these documents promotors of in-house AP labs use to convince specialist physician groups to invest in an AP laboratory.

The 12-Core Controversy

One example of an AP lab condo financial projection is found on pages 11-12 of this issue. Prepared for urology practices, it bases revenues on 100% utilization of a 12-core prostate biopsy. That raises a red flag for pathologists. Within the United States, there is no clinical standard which supports performing a 12-core prostate biopsy on 100% of patients undergoing this procedure.

Were a urology group to adopt a clinical standard of ordering 12-core biopsies for every patient requiring a prostate biopsy from its own in-house anatomic pathology laboratory, two negative outcomes may result.

First is the patient care issue. Was the patient needlessly subjected to 12 fine needle punches, with the resulting increased morbidity, bleeding, and pain, simply because urologists had an incentive to self-refer a case which maximized revenues to their group practice? Second, since Medicare, Medicaid, and private payers reimburse for each individual analysis of a biopsy core, ordering a prostate biopsy with 12 identifiable cores is a way to generate additional revenue to the specialist group practice.

That revenue impact is substantial. Today, evidence exists that the majority of prostate biopsies involve diagnosing six or fewer cores. If the example of \$100 reimbursement per biopsy core (slide) is used (technical and professional), a six-core prostate biopsy would be reimbursed at \$600. A 12-core prostate biopsy would double that to \$1,200.

In this issue, THE DARK REPORT is publishing evidence that some promot-

ers of in-house AP laboratories do rely on 100% utilization of 12-core prostate biopsies to justify the financial investment for prospective specialist physician groups. (*See pages 8-12.*)

To identify the existing standard-ofpractice within the anatomic pathology profession, THE DARK REPORT contacted **Pathology Service Associates, LLC** (PSA), based in Florence, South Carolina. The results will interest even veteran anatomic pathologists.

Survey Of Billing Data

"PSA is a member network of 71 pathology group practices and represents more than 400 pathologists in 21 states," stated Louis D. Wright, Jr., M.D., Founder. "PSA handles billing for a substantial number of our member practices, so we do service a representative slice of the AP profession.

"At your request, we did a study of prostate biopsy claims filed by our member groups during the first six months of this year, from January 1 to June 30, 2004," he continued. "Our records show 8,663 prostate biopsy patients. A total of 39,733 needle biopsies for these patients were submitted as separately identified for evaluation.

Number of Cores

"Our study indicated an average of 4.6 billable CPTs per patient were generated for this procedure," stated Wright. "This is an average of *billable* CPTs, which includes cases where the referring physician has sent a right hemisphere bottle and a left hemisphere bottle, each containing three cores. Although the pathologist performed six evaluations for this case, it is properly submitted as two billable 88305 claims.

"I want to stress that this average of 4.6 billable CPT codes reflects what the physicians order our pathologists to evaluate," noted Wright. "We consider this to be a reasonable reflection of what is happening in the local healthcare community. It indicates that, within the urology community, 12-core prostate biopsies are not the standard."

"To the contrary," he added, "a much smaller number of biopsies per case is typical. We excluded prostate biopsy cases that originated within hospitals, so our number is based exclusively on biopsies ordered by office-based physicians."

"At your request, we also looked at how frequently a 12-core prostate biopsy was ordered," said PSA CEO Al Sirmon. "Of the 8,663 patients, 3% of the test orders separately identify more than 12 cores and 7% separately identify 12-cores. Combined, that indicates that physicians across the country separately identify and submit 12-core prostate biopsies on about 10% of their patients."

3% of Nation's Biopsies

During 2004, the **Prostate Cancer Foundation** estimates 230,000 new cases will be diagnosed. Assume a 40% positive rate on all patients undergoing a biopsy. That projects to about 575,000 patient biopsies in 2004. PSA's 8,663 patient claims during the first six months of 2004 indicates it may be billing for 3.01% of all prostate biopsies diagnosed annually. Although not the result of a rigorous scientific study, these numbers do provide a reliable insight into existing ordering patterns for prostate biopsies.

THE DARK REPORT observes that a 12-core prostate biopsy does increase a specialty group's revenue. But it also increases the reimbursement paid by Medicare and Medicaid to settle these claims. It may not take long for federal healthcare fraud investigators to pick up this pattern and take enforcement action. Specialists physicians should be forewarned. The last time the lab industry faced comparable Medicare Fraud and Abuse charges, it paid more than \$1 billion in restitution and fines! TDR Contact Louis D. Wright, Jr., M.D. and Al Sirmon at 800-832-5270.

Exposed: Who Created Path Lab Condo Scheme

Urologists in Florida and Texas are progenitors and promoters of this ploy

CEO SUMMARY: It wasn't pathologists and it wasn't laboratory executives who started this scheme. Anatomic pathology condominium laboratory complexes were conceived by urologists in Florida. Some Texas urologists jumped on the bandwagon early, becoming enthusiastic promoters of the scheme to other specialist physicians. That's why Florida and Texas are the hotbed states for this movement.

BECAUSE ORGANIZERS of pathology condominium laboratory complexes go to unusual lengths to keep their businesses hidden from public view, few people know much about them.

THE DARK REPORT, with this intelligence briefing, begins the process of exposing their business scheme to public scrutiny. The fact that these companies work hard to keep the details of their business secret is a contradiction to the principle that physicians, patients, health insurers, and government health programs should operate in a transparent manner.

Tough Detective Work

The information which follows was collected from a wide range of sources, both public and private. The general story about how the business scheme of a pathology condominium laboratory was cooked up, who contributed, and how it was expanded is believed to be reasonably complete.

However, some of the details presented here may not be completely accurate. This is because much of the information known about pathology lab condo complexes comes from individuals not employed within these businesses.

In particular, it must be emphasized that every attempt to speak with any employee connected with a pathology lab condominium or anyone affiliated with a urology or gastroenterology group that owns an AP lab condo was met with a universal response: "Who are you? We have nothing to say." In today's world of instant communications and Internet access to company Web sites, this absolute Wall of Silence is extraordinary.

THE DARK REPORT believes the story of the pathology condominium laboratory complex scheme begins in Ocala, Florida. Two urologists at the **Urology Center of Florida**, D. Russell Locke, M.D. and Ira W. Klimberg, M.D. can probably be credited as the individuals who conceptualized the business potential of selling anatomic pathology (AP) condominium laboratories to other urology and specialist physician groups.

17 / THE DARK REPORT / August 9, 2004

In April 1996, Locke and Klimberg formed a pathology laboratory company called **CytoCor**, **Inc.** (aka **CytoCor Diagnostic Laboratory Services**). It performed anatomic pathology testing for Urology Center of Florida on specimens generated by the patients of Locke and Klimberg. CytoCor still operates and provides technical services for at least two subsequent pathology lab condominium complexes now in operation.

In the years following 1996, CytoCor began providing services to other specialist groups. This experience, combined with certain new regulatory opinions affecting physician group ownership of ancillary services, led Locke and Klimberg to create the concept of the AP laboratory condominium complex. The individual lab condos would be sold to any interested specialist groups.

In January 2002, Locke and Klimberg formed **Trover**, **Inc.** as the vehicle to sell the AP laboratory condominium concept to other urology groups. Trover changed its name in August 2002 to **Physicians RightPath**, **LLC**. It has the only Web site operated by an AP lab condominium operator, at *www.physiciansrightpath.com*.

Two Lab Condo Complexes Physicians RightPath operates an AP laboratory condo complex in Ocala that, at one time, contained as many as six individual laboratories. It built an AP condominium complex in Tampa, Florida. As many as six AP lab condos may be in operation at the Tampa site.

In 2001, the pathologist and the practice administrator left Locke and Klimburg's employ. Both took positions at **Atlantic Urologic Associates** (AUA), located in Daytona Beach. The pathologist is Nicholas A. Maruniak, M.D., who still works in enterprises related to AUA. The practice administrator is Chris Hill.

In combination with urologists at AUA, Maruniak and a group of Texas urologists from **Urology Associates of North Texas** (located in Dallas) started their own company to promote and operate pathology laboratory condo complexes in February 2002. It took the name **UroPath, LLC** in June 2003.

During the second half of 2003, UroPath began to actively solicit urology and gastroenterology group practices in a number of states.

This AP lab condo complex was located in Leesburg, Florida. It managed anatomic pathology lab condos for specialist group owners located in Texas and several other states. Maruniak was the pathologist for the AP lab condos in that complex.

Based on information gathered from a variety of sources, it appears the Texas urologists took the AP laboratory condominium complex idea to a higher level. They decided they could package and sell AP lab condos to specialist physicians across the United States. UroPath LLC was the business vehicle to accomplish that goal.

During the second half of 2003, UroPath began to actively solicit urology and gastroenterology group practices in a number of states. UroPath would provide a turnkey development and operating solution for any group of specialist physicians wanting to profit from anatomic pathology services generated by their patients.

In addition to the Dallas urologists, another physician group in Texas caught "AP pathology condo lab fever." **Urology San Antonio** purchased an AP laboratory condominium in Florida. The medical director was Maruniak. The financial performance of their AP lab condo was spectacular enough for Urology San Antonio to build an entire AP lab condo complex in San Antonio. It is located in a building they purchased next to their main urology clinic. The laboratory is operated by UroPath, LLC and has at least eight separate lab condominiums in operation. (*Read about THE DARK REPORT'S site visit to this AP lab condo complex in July on pages 21-22.*)

One enthusiastic booster of urologists capturing anatomic pathology work generated by their patients is Juan A. Reyna, M.D., a partner at Urology San Antonio. UroPath sells this concept by having participating urologists, like Reyna, do sidebar presentations at national and regional urology meetings. The sales process is done urologist-to-urologist, with virtually no marketing materials provided to prospects.

In addition to the San Antonio facility, UroPath is currently building another AP lab condominium complex in Dallas. UroPath's corporate office is also in Dallas and its President is Ken Flowers.

UroPath Becomes UniPath

For a four-month period, from December 2003 through March 2004, UroPath operated under the name **UniPath, LLC**. This name was considered to be more inclusive for gastroenterologists and other types of specialist physicians. But conflicts with an existing UniPath corporate registration in Texas and another UniPath in Colorado caused the company to return to its UroPath, LLC name.

The success enjoyed by Physicians RightPath and UroPath in selling between 25 and 50 AP laboratory condominiums did not go unnoticed by others. Another company now selling AP laboratory condominiums is **Gulf Coast Medical, Inc.**, located in the Clearwater, Florida area. It is now building a clinical laboratory facility. It may launch its AP condo lab complex with two lab condos, one owned by a dermatology group practice.

The President of Gulf Coast Medical is Morris Behar. He's been active in the laboratory industry in Florida for a number of years and was formerly with **Med Tech Labs, Inc.**, which was acquired and renamed **VitalLabs, Inc.** in 2002. (*See TDR, July 15, 2002.*) VitalLabs has since gone out of business.

Lab Condo Complex Sites

THE DARK REPORT has seen a list circulated by UroPath, LLC in which it states it is operating or building AP lab condo complexes in the following cities: Leesburg, Florida (10 labs), Sarasota, Florida (10 labs), San Antonio, Texas (12 labs), and Dallas, Texas (15 labs). These numbers could reflect commitments to buy, could be marketing hype, or a combination of both. Collectively, these numbers total 47 individual labs. If accurate, that would be a remarkable number for a company operating only 30 months.

The sales campaign by these companies has attracted the attention of specialist groups in many states. In Kansas City, Missouri, a urology group and a gastroenterology group each acknowledges ownership of a "stall-in-a-barn AP lab" in Florida (as characterized by a physician in one of these groups). Specialist groups in states like Indiana and South Carolina are known to be considering buying an AP lab condo.

On the following two pages, THE DARK REPORT presents a family tree and timeline showing development of the AP laboratory condominium complex scheme. Compiled from many sources, this information is believed to provide a reasonably accurate picture, although some specifics may be inaccurate. **TDR**

Tracking the Family Tree for Pathology Lab Condominiums

Progenitor:

April 1996: Ira W. Klimberg, MD and Russell D. Locke, MD of Urology Center of Central Florida in Ocala, FL build an in-house anatomic pathology (AP) laboratory. CytoCor, Inc. is its operating name. Locke and Klimberg develop business concept of AP laboratory condominium.

2001: Pathologist Nicholas Maruniak, M.D.V and Practice Administrator Chris Hill leave the employ of CytoCor and move to Atlantic Urological Associates, Daytona Beach, FL.

Jan 2002: Trover, Inc. established to market and develop AP laboratory condos to other specialist groups practices. Later changed to Trover, LLC.

Aug 2002: Physicians RightPath, LLC formed as the marketing and development company to recruit other group practices to establish pathology lab condos to be managed by Physicians RightPath. CEO is Christopher Bryant.

2003: Physicians RightPath develops a pathology condominium complex in Ocala, FL and manages as many as six individual AP laboratory condominiums. CytoCor provides technical services to the AP lab condos. Those lab condos provide anatomic pathology professional services to the specialist groups which own them.

2004: Physicians RightPath constructs a pathology condominium complex in Tampa, FL and operates several individual AP laboratory condominiums.

THIS FAMILY TREE is the product of extensive research and lots of investigation. THE DARK REPORT believes it is comprehensive and identifies all the companies known to be operating and promoting anatomic pathology laboratory condominium ventures to specialist physicians.

Collectively, the number of AP laboratory condos either in operation, under construction, or contractually committed may total as many as 50. For an ancillary services business concept that was only launched about 24 months ago, this is explosive growth. To this number must be

added those specialist groups which built their own AP lab within the walls of their clinic

Indirect

Progeny:

Now Organizing

during the same period. An estimate of 30 to 50 would be justified, based on anecdotal comments from pathology practices which lost these groups as clients. Together, there is market evidence that, over the past 24 months, upwards of 100 specialist groups actively committed to internalizing AP testing.

This family tree demonstrates that the phenomenon of AP lab condos is currently limited to two significant promoters. Specialist interest in this scheme can be expected to continue so long as existing path lab condo owners boast of ample profits and federal healthcare regulators take no effective enforcement action.

Direct Progeny:

2001: Pathologist Nicholas Maruniak, M.D. and Practice Administrator Chris Hill join Atlantic Urological Associates, Daytona Beach, FL. Maruniak incorporates Nicholas A. Maruniak, MD, PA in September 2001.

February 2002: Atlantic Urological Associates develops its own pathology condominium laboratory business in a venture that includes Urology Associates of North Texas, LLP, based in Dallas. H. Patterson Hezmall, MD is the President. The AP lab condo is located in Leesburg, FL.

June 2003: UroPath, LLC incorporated in Texas. Hezmall and Steve Kamber are officers or agents.

December 2003: UroPath, LLC registers a name change in Texas and Florida as UniPath, LLC. Hezmall and Michael S. Grable, MD of Daytona Beach, FL are managing members.

March 2004: Unipath, LLC registers a name change back to UroPath, LLC in Texas and Florida.

August 2004: Gulf Coast Medical, Inc. is developing an AP laboratory condominium complex in Clearwater, FL, as part of a new clinical laboratory currently under construction. It will start with two AP lab condos, including one dermatopathology lab. Morris Behar is the primary organizer of this business.

August 2004: UroPath, LLC operates AP laboratory condo complexes in Leesburg, FL and San Antonio, TX. Another AP lab condo complex is opening in Dallas, TX. Ken Flowers is UroPath's President, with offices in Dallas.

Visit To A Path Condo Lab: "You Are Not Welcome"

Our visit to an AP lab condo complex demonstrates its secretive nature

O "WELCOME MAT" greets visitors to an anatomic pathology (AP) condominium complex. That was certainly true last month when an agent of THE DARK REPORT attempted to visit a lab condo complex in San Antonio, Texas.

Operated by **UroPath, LLC**, the lab condo complex is located at 7909 Fredericksburg Road in Suite 150. Also in that same office park are the offices and ancillary service facilities for **Urology San Antonio**, one of the promoters of the AP lab condo scheme.

Entering through a doorway underneath a large UroPath sign, our agent asked to speak to the facility manager to express his interest in the business and to have an impromptu tour. The receptionist was emphatic that no walk-in visitors could ever be accommodated. He would have to make a telephone appointment.

Not Allowed Past The Lobby Ever resourceful, our agent returned to his car in the parking lot. Using his cell phone, he called the receptionist to make an appointment. After considerable pressure, he was allowed to return and at least meet the facility manager in the reception area. Feigning a busy schedule, the UroPath site manager refused to answer any questions, but did provide her business card and wrote the name and number of the UroPath's business development representative on the back. During the time our agent was in the lobby, he observed that there was a hall of doors. Each door had the name of a different urology group's laboratory on it. He watched as people with lab coats would emerge from one door, walk down the hall, and enter another door.

As a veteran of four decades in the lab industry, our agent made a blunt statement about his visit. "This pathology laboratory condo scheme is mindboggling!" he declared. "I can assume that they have carefully structured this to fit within the boundaries of the law. But is it on the fringe of legal?

Meets Law But Not Intent

"In my view, it violates the intent of anti-kickback and Medicare fraud and abuse statutes," he continued. "Whenever federal healthcare investigators take a serious look at these laboratory condo arrangements, the fact that they have stretched the intent beyond established norms may drive enforcement action. If that happens, it usually hurts the entire laboratory industry."

Our agent did relay the news that, during his conversation with the UroPath site manager, he was told that UroPath is building another AP lab condo complex in Dallas. Further, the site manager stated that "there has been an overwhelming response" by the urology profession to the financial benefits of a group owning its own AP laboratory condominium.

UroPath's AP Lab Condominium Complex Operates in San Antonio, Texas

This is the anatomic pathology laboratory condominium complex operated by UroPath, LLC. It is located at 7909 Fredericksburg Road, Suite 150, in San Antonio, Texas. This shows the front entrance into a standard office park building.





In approaching the front door, the laboratory complex is identified as UroPath, LLC. This is the management entity which operates the AP labs inside for the different specialist group owners.

This close-up of the names on the window to the right of the door shows that eight different urology groups each own an AP laboratory condominium in this complex. It appears only one San Antonio urology group owns a lab in this complex. The other urology groups are located as far away as Amarillo and Dallas.

OPATH LLC LABORATORY MANAGEMENT

AMARILLO UROLOGY ASSOCIATES LABORATORY LUBBOCK UROLOGY CLINIC LABORATORY MEMORIAL UROLOGY ASSOCIATES LABORATORY UROLOGIC CONSULTANTS OF HOUSTON LABORATORY UROLOGY ASSOCIATES OF SOUTH TEXAS LABORATORY UROLOGY SAN ANTONIO LABORATORY THE UROLOGY TEAM LABORATORY UROLOGY TYLER LABORATORY



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