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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

A Pantheon of Greatest Lab Physician-Businessmen

WHEN IT COMES TO THE CLINICAL LABORATORY BUSINESS, generally included in the lab industry's Pantheon of Greatest Physician (Pathologist) Businessmen are Paul A. Brown, MD, and James B. Powell, MD. I'd like to nominate another physician to this list: Marc D. Grodman, MD.

During the 1970s and 1980s, Brown and Powell—both pathologists—founded and led two of the nation's most successful laboratory companies. It was in 1967 when Brown founded **MetPath**, the laboratory company acquired for $140 million by **Corning Corporation** in 1982. Brown left MetPath shortly thereafter. In 1996, Corning spun off this lab division, creating **Quest Diagnostics Incorporated**.

Along with his two brothers, Powell launched **Biomedical Reference Laboratories** in 1969 in North Carolina. In 1979, Biomedical went public and was valued at about $50 million. Just three years later, in 1982, **Hoffman-La Roche** purchased the lab for $163.5 million. It was merged with another lab division and became **Roche Biomedical Laboratories**. Powell stayed on as CEO. In 1994, **National Health Laboratories** acquired a majority interest in Roche Biomedical and the merged lab company was renamed **Laboratory Corporation of America**. Powell continued as CEO, retiring in 1997.

What qualifies Grodman to be associated with these two physician lions of the laboratory industry is his sustained business successes over the past 35 years. Trained in internal medicine, Grodman founded **Bio-Reference Laboratories** in New York City in 1981. It grew steadily and, by the late 1990s, was a public company with annual revenue of about $60 million.

Through the decade of the 2000s—a time of intense price pressure and bitter managed care contract wars triggered by the two blood brothers—Bio-Reference posted an impressive track record of double-digit growth in specimen volume and revenue. Grodman did this with different business strategies than his major competitors—and without the need for serial lab acquisitions. Moreover, throughout this time, unlike its other public lab company peers, BRLI never settled a federal whistleblower lawsuit.

Last year, BRLI posted revenue of $832 million and is the nation's third-largest lab company. These accomplishments surely make Grodman worthy of inclusion in the lab industry's Pantheon of Greatest Physician Businessmen. TDR

Understanding the Future Of Laboratory Medicine

Innovators at the leading edge of diagnostics will share successes and lessons learned in April

CEO SUMMARY: Healthcare's transformation is now far enough along that most clinical labs and pathology groups are either feeling the financial pain or are excitedly developing ways to deliver more value from lab testing services. On April 26-27, at the 21st annual Executive War College on Lab and Pathology Management, expert speakers will address how their labs are responding to the threats and opportunities, while explaining how other labs can duplicate their clinical and financial successes.

MONTH-BY-MONTH, a cascade of new insights emerges from ongoing research into the various "omes" of humans. Consequently, clinical labs and pathology groups are being handed new tools to use to achieve earlier diagnosis and to contribute to precision medicine.

The pace with which this new knowledge is being adopted in support of clinical care is without precedent. Clinical labs and pathology groups are not the only sectors of healthcare struggling to keep up with these developments. Hospital administrators, physicians, payers, and healthcare policymakers are all overwhelmed by both the speed of change and the sheer volume of new knowledge capable of improving healthcare and delivering better outcomes for patients.

This flood of knowledge is spilling out of research into various "omes" of humans. Take your pick: genome, proteome, transcriptome, microbiome, metabolome, epigenome, pharmacogenome. All are producing tens of thousands of new biomarkers that have the potential to be used by clinical labs to diagnose disease earlier and more accurately, to identify effective therapies for individual patients, and to monitor a patient's progress over time.

Recognizing that the river of clinical knowledge flowing from research into these "omes" is fully disruptive to the world of laboratory medicine as we know it today, this year's *Executive War College on Laboratory and Pathology Medicine*, scheduled for April 26-27, 2016, has confirmed experts in all dimensions of the

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fast-moving fields of molecular diagnostics and genetic testing. These experts will discuss advances in molecular and gene sequencing technologies, how health insurers and the Medicare program are dealing with new lab tests, why labs need more information technology to handle this data, and what innovative clinical labs are already doing to use these new diagnostic insights to deliver more value to physicians, payers, and patients.

Whole Human Genomes

There is plenty of news about advances in whole human genome sequencing and that topic will be front-and-center at the *Executive War College*. Speakers from two of world's largest efforts to sequence and study large numbers of whole human genomes will provide pathologists and lab managers with an inside look at the early discoveries.

Brad Perkins, MD, is the Chief Medical Officer of **Human Longevity, Inc.**, based in San Diego. This company was founded by C. Craig Venter, PhD, and Peter H. Diamandis, MD, Founder and CEO of the **X PRIZE Foundation**.

Perkins will discuss how his company has already sequenced 24,000 whole human genomes and is now interpreting that data to identify knowledge that can be introduced into new clinical care pathways in support of both population health management and precision medicine.

UK's 100,000 Genomes

Following his presentation, Professor Sue Hill, Clinical Lead for the **National Health Service** in the United Kingdom, will speak. She is involved with the globally-famous **100,000 Genomes Project**.

Genomics England, a company wholly owned and funded by the **UK's Department of Health**, was established to do the work necessary to sequence 100,000 whole genomes from approximately 70,000 NHS patients by 2017. The participants are NHS patients with a rare disease, plus their families, and patients with cancer.

As clinically-actionable knowledge emerges from the 100,000 Genomes Project, Hill is one of the individuals responsible for developing new clinical pathways and helping to introduce them to physicians in the United Kingdom.

Together, the presentations of Perkins and Hill will give attendees an unprecedented understanding of the current state of the art of whole human genome sequencing—ranging from the cost and operational needs for high volume sequencing to the challenges of collecting the data, storing the data, and interpreting the data to find opportunities for clinical action.

Molecular Diagnostics

Moving from the high-level perspective on genetic medicine to the practical level, in the area of molecular diagnostics and genetic testing, Wayne Grody, MD, PhD, will deliver a session designed to help lab managers in community hospitals understand what new tests are delivering the most value to clinicians.

Grody is Director of the Diagnostic Molecular Pathology Laboratory within the **UCLA Medical Center** and a Professor in the Departments of Pathology & Laboratory Medicine, Pediatrics, and Human Genetics at the **UCLA School of Medicine**. In his work, he interacts regularly with community hospitals and thus sees what types of molecular assays and genetic tests are delivering the most clinical value and would be useful for these hospital labs to perform internally.

Additionally, Grody will address the steady flow of new molecular and genetic testing instruments and systems. Not only are these becoming cheaper for hospital labs to purchase, but they feature more automation and accuracy. Their "load and walk-away" features make it feasible for even smaller community hospitals to buy these instruments so as to reduce turn-

Is the End of Private Practice Pathology Here? Experts to Address this Trend on April 28

BIG CHANGES ARE HAPPENING TO MANY PRIVATE PATHOLOGY GROUP PRACTICES. One-by-one, across the nation, pathology groups are hitting a financial wall that undermines their ability to deliver the quality and breadth of the clinical services they see as necessary to serve their hospitals and client physicians.

But as financially painful as these market trends are, most pathology practice administrators and their pathologist-business leaders still fail to recognize that these are fundamental shifts in the healthcare marketplace. Consequently, these pathology groups often find themselves too far down the road of financial erosion to turn the situation around and restore their pathology practice to solid fiscal solvency.

To address this situation, the organizers of this year's *Executive War College* have scheduled a one-day think tank on the fate of private pathology groups. It is titled, "Private Practice Pathology's Present and Future: What's Working… What's Not… with Strategies to Protect and Enhance Pathologist Income." It will take place on April 28, 2016, in New Orleans.

The workshop is designed to be a must-attend for pathologists who are the business leaders of their groups, along with their practice administrators. Academic pathology groups will also find this to be essential information.

Groups Still Make Money

Successful regional pathology groups, such as **Pathology Specialists of Arizona LLP**, will discuss their most productive business and clinical strategies. PSA already serves ACOs with large enrollments and is aggressively contracting with managed care plans—particularly the Medicare Advantage plans that have significant market share in Arizona.

An open forum panel discussion will take place that includes attorney Jane Pine Wood, noted legal specialist in pathology and clinical laboratory, Robert Tessier of **HBP Services**, and an executive from **McKesson Revenue Management Solutions**, one of the nation's largest companies providing billing services to anatomic pathology groups and clinical labs. During this session, attendees will interact directly to gain answers and insights into issues specific to their payers, their region, the Medicare program, and more.

Strengthening Finances

For pathology groups considering strategic business options, attorney Rick Cooper of **McDonald Hopkins** will cover the range of opportunities. Does it make sense to merge with a larger group in the region? What prices are pathology group buyers paying? How should pathologists assess opportunities to sell or transition to employee status?

Two pathology consultants, Tessier and Mick Raich of **Vachette Business Services**, will share data and advise on specific opportunities to boost the group's revenue and financial strength. Tessier will demonstrate how public access to Medicare physician price data can help a group negotiate better Part A agreements with hospitals. He will also show the findings of a national pathologist workload study that can help groups balance workload and compensation more effectively.

Raich will speak to how pathology groups can tap overlooked sources of revenue, something he does regularly for his client groups. His topics will include Part A compensation, new managed care opportunities, changes in how to bill payers, and Medicare's switch from PQRS to MIPS.

Space does not allow full details about Rich Cornell, who will discuss the current pathology job market, or Leigh Polk on how to assess the sales and revenue potential for a pathology group's service market—then implement a plan to harvest that additional revenue. The full agenda, speakers, and registration details are at *www.executivewarcollege.com*.

around time and deliver more value in support of inpatient diagnosis and treatment.

Two topics of interest to every pathologist and lab executive is PAMA lab test price market reporting and the FDA's guidelines for regulating laboratory-developed tests (LDTs). Those subjects will be front and center during a panel discussion that brings together experts from the **American Clinical Laboratory Association**, **AdvaMedDx**, **College of American Pathologists**, and **National Independent Laboratory Association**.

Congress, CMS, And FDA

This is the only time and the only place where all these experts come together. They are the individuals tasked by their respective organizations with lobbying Congress on these issues and working with federal regulators to educate them about what labs need to operate efficiently in support of improved patient care.

Thus, they know what is shaping bills in Congress that deal with clinical lab testing and anatomic pathology services. They also participate in meetings with CMS and the FDA on proposed regulations that would govern lab tests. This provides the audience with an insider's perspective on what is unfolding within the government, why it is happening, and who is supporting or opposing these bills or regulations.

Managed care issues involving billing, coding, audits, network agreements , and coverage for molecular and genetic tests, are also topics of high interest. These topics also represent additional revenue to the lab when the lab team understands how to work with payers to meet changing criteria. A panel of managed care experts will take up these subjects and will include executives from **Aetna, Inc.**, and **Blue Cross Blue Shield of Louisiana**.

There will be more than 60 sessions and 100 speakers at this year's *Executive War College*. The agenda can be found at *www.executivewarcollege.com*. TDR

For Labs Needing Revenue: Good Selling Still Pays Off

IT IS POPULAR WISDOM across both the clinical lab and anatomic pathology sectors that sales programs are becoming ineffective ways to build revenue, improve profit margins, and increase the number of client physicians.

That popular wisdom is only partially right. It is correct that a poorly-designed sales program now generates disappointing financial results. It is also correct that hiring average sales reps and then not managing them also produces poor results in today's tougher financial marketplace.

But what is equally true is that there are clinical labs, specialty testing labs, and anatomic pathology groups that have sales programs that continue to generate profitable new business. What these labs have in common that makes their sales programs financially successful will be taught at the upcoming *Executive War College*.

The first learning opportunity is the two-hour roundtable discussion conducted by Lab Vice Presidents for Sales and Marketing for Lab Sales VPs and lab managers responsible for managing their lab's sales reps.

The second learning opportunity is a full-day workshop, titled "Using Sales Performance Coaching to Boost Revenue and New Clients for Clinical Labs, Pathology Groups, all Specialty and Genetic Testing Labs." It will be led by Jock Murray, President of the **Jock Murray Group, LLC,** and will take place on April 28.

Whether experienced at sales management or relatively inexperienced, this workshop teaches coaching as a process of equipping people with the tools, knowledge, and opportunities that they need to develop themselves. This workshop provides sales managers coaching knowledge and strategies, opportunities to practice coaching conversations, and development of coaching strategies for specific sales team members.

Dark Index

Grodman Resigns from BRLI, New President Is Henderson

New president is only the second at Bio-Reference since Grodman founded the lab company in 1981

THERE IS A NEW LEADER at **Bio-Reference Laboratories, Inc.**, now owned by **OPKO Health, Inc.**, of Miami, Florida. Last week, Gregory Henderson, MD, PhD, was named as President of BRLI.

Henderson takes over from Marc Grodman, MD, who resigned after serving as Chairman, President, and CEO of Bio-Reference Laboratories since 1981, a company he founded that same year.

OPKO Health acquired BRLI in August 2015, in a deal valued at $1.47 billion. BRLI is the nation's third largest full-service clinical laboratory. This deal attracted attention on Wall Street because OPKO, a multinational biopharmaceutical and diagnostics company, was making a major investment to enter the clinical diagnostics business.

Vice Chair of Outreach

Before being named BRLI's president, Henderson was Vice Chairman of Pathology Outreach and Affiliate Laboratory Affairs for **Mount Sinai Health Network** in New York. MSHN runs one of the largest hospital-based laboratory outreach programs in the United States.

A practicing pathologist with more than 20 years of experience, Henderson previously founded **NextWave Diagnostic Laboratory**, in Wilmington, North Carolina, and **Pacific Pathology Partners**, in Seattle. He has since sold both clinical lab companies.

Grodman made an indelible mark on the clinical laboratory industry. He grew BRLI from a company generating less than $60 million in revenue in 1999 to one that became the third-largest publicly-traded clinical lab company in the United States. Last year, BRLI generated $832 million in revenue. Most of the growth that BRLI achieved under Grodman was through conventional sales and marketing and not through acquisitions.

One impressive metric to note is the BRLI's revenue per accession of approximately $87 is almost double that of other public lab companies, in part because BRLI under Grodman developed molecular and esoteric tests that clinicians found to be useful.

A practicing internal medicine physician, Grodman sees patients as an Assistant Attending Physician at **Presbyterian Hospital**, in New York, and serves on the faculty as an Assistant Professor of Clinical Medicine at **Columbia University College of Physicians and Surgeons**.

Grodman received a bachelor's degree from the **University of Pennsylvania in** 1973 and an MD degree from Columbia University College of Physicians and Surgeons in 1977. From 1980 to 1983, he attended the Kennedy School of Government at **Harvard University** and was a primary care clinical fellow at **Massachusetts General Hospital**. **TDR**

—Joseph Burns

Digital Pathology Venture Improves Patient Care

➤Partnership between UPMC and KingMed uses telepathology to improve patient outcomes in China

➤➤CEO SUMMARY: Many experts think that digital pathology will make it possible to create international pathology subspecialty referral networks. Now in its fifth year, a partnership between UPMC's Pathology Department and KingMed Diagnostics of China uses telepathology to give Chinese patients access to the subspecialist pathologists at UPMC. KingMed's case referrals to UPMC rose from 144 in 2012 to 810 last year and data show that patient outcomes are improving because of this telepathology service.

TWO FRONTIERS LOOM as opportunities for the anatomic pathology profession. One frontier is the regular use of digital pathology in support of clinical care. The other frontier is the opportunity to generate specimens and revenue from pathology cases referred to labs in the United States from other countries.

Both frontiers are being explored in a partnership between **UPMC International** and **KingMed Diagnostics** in China. Now in its fifth year, the partnership has demonstrated solid growth for UPMC's Pathology Department.

In 2012, the first year of the program, UPMC pathologists reviewed 144 specimens. This year, specimen volume will total more than 800 cases, stated Liron Pantanowitz, MD, Professor of Pathology and Director of Pathology Informatics and Cytopathology at **UPMC Shadyside**.

Improving patient care is a primary goal of this partnership because patients in China have limited access to the subspecialist pathology expertise that exists here in the United States. According to a study published in the *Journal of Pathology Informatics* in November, Pantanowitz and colleagues explained how international telepathology consultations had significantly improved patient care.

Over the first three years of the partnership with KingMed, China's largest diagnostics company, the two partners reviewed more than 1,500 pathology cases submitted electronically to UPMC. The journal authors determined that consultation with UPMC subspecialist pathologists resulted in significantly altered treatment plans for more than half of the cases in which clinicians in referring hospitals in China provided a patient's primary diagnosis.

➤Telepathology for NGS

"Now we are expanding our anatomical pathology telepathology services to other clients in China," stated Pantanowitz. "Also, our telepathology team is working on molecular telepathology for next-generation sequencing for our clients here in the United States.

"The experience with KingMed prompted us to streamline and improve

Case Referrals from China to UPMC Pathologists Demonstrate the Benefits of Subspecialty Expertise

PATHOLOGISTS INVOLVED IN THE GROUND-BREAKING JOINT VENTURE between the University of Pittsburgh Medical Center Department of Pathology and KingMed Diagnostics of China recently published an analysis of the pathology cases handled by the two partners since the start of the relationship in 2012.

Table A shows that, in more than 50% of the cases, UPMC's pathologists provided a diagnosis that significantly disagreed with that of the referring pathologists. **Table B** shows the sources of referred cases. **Table C** reports on the types of diagnoses for these cases. **Table D** provides a breakdown of the types of cases and the percentages of disagreement. This information was published in the *Journal of Pathology Informatics. (J Pathol Inform 2015, 1:63.)*

A. Agreement of diagnoses between UPMC expert pathologists and the primary pathologists in China

Diagnostic agreement	Case number	Percent
Identical diagnosis	219	25.6%
Diagnosis slightly modified	202	23.6%
Diagnosis significantly modified (disagreed)	434	50.8%
Total	**855**	**100%**

B. Referral nature of cases submitted for telepathology consultation Individuals requesting

Consultation	Case number	Percent
Primary pathologists in China	958	61.4%
Clinicians in China	576	36.9%
Patients in China	27	1.7%
Total	**1,561**	**100%**

C. Diagnostic entities rendered by UPMC expert pathologists

Diagnostic lesion	Case number	Percent
Malignant	969	62.1%
Neoplasm (includes borderline tumors)	225	14.4%
Benign	367	23.5%
Total	**1,561**	**100%**

D. Referral nature of cases submitted for telepathology consultation

Pathology subspecialty	Total case number	Cases submitted with primary diagnosis (%)	Cases with significant disagreement (%)
Hematopathology	370	169 (45.7%)	90 (53.3%)
Bone/soft tissue	327	143 (43.7%)	80 (55.9%)
Gynecology/breast	316	188 (59.5%)	78 (41.5%)
Head/endocrine	117	99 (84.6%)	72 (72.7%)
Gastrointestinal	113	75 (66.4%)	33 (44.0%)
Dermatopathology	105	52 (49.5%)	29 (55.8%)
Thoracic	65	48 (73.9%)	20 (41.2%)
Genitourinary	59	29 (49.2%)	12 (41.4%)
Neuropathology	46	32 (69.6%)	12 (37.5%)
Liver	29	13 (44.8%)	6 (46.2%)
Pediatric	9	4 (44.4%)	1 (25.5%)
Other (misc.)	5	3 (60.0%)	1 (33.3%)
Total	**1,561**	**855 (54.8%)**	**434 (50.8%)**

our digital consultation portal. Now we are discussing comparable situations with India, Italy, and Kazakhstan," said George Michalopoulus, MD, PhD, the Maud L. Menten Professor of Pathology and Chairman of the Department of Pathology.

"After reviewing 144 cases in 2012, our UPMC pathologists saw specimens referred from China rise to 614 in 2013, 803 in 2014, and 810 last year," Pantanowitz added. "Most of these pathology cases were hematopathology

specimens, followed by bone or soft tissue and then gynecologic or breast specimens. We expect to review more than 800 cases this year."

To achieve these successes, the UPMC-KingMed partnership had to address three significant challenges involving training, workflow, administration, and information technology, Pantanowitz commented. "First, pathologists had to be trained and had to establish a suitable workflow to comfortably and confidently perform teleconsultation using whole slide images," he said.

Partnering With IT Staff

"Second, under administration, we had to appropriately triage consults, handle billing, and manage issues related to digital consults (such as timely troubleshooting)," he said. "Third were the IT challenges. These included partnering with UPMC IT staff from our information services division (ISD) with varied skill sets (such as web designers and programmers) to build, continually customize, and maintain our in-house telepathology system," he explained.

By addressing the workflow issues successfully, the Pathology Department did not need to add pathologists to accommodate the increased workload each year. "Consults were routed only to subspecialists at our academic hospitals who already had these subspecialty skills and are well known experts in their respective fields," Pantanowitz commented.

"And we did not need to add overnight shifts or extend hours for our pathologists, in part because our telepathology system allows our pathologists to consult from anywhere at anytime," he added.

One key to smoothing the workflow process was appointing Chengquan Zhao, MD, a native of China who speaks fluent Mandarin, to manage all correspondence between the two partners, Pantanowitz said. A UPMC Professor of Pathology, Zhao is a member of the Division of Gynecologic Pathology and Associate Director of Cytopathology and Director of Fine Needle Aspiration at **UPMC's Magee-Womens Hospital**.

"All key correspondence was and still is handled by Professor Zhao," Pantanowitz explained. "He takes care of all communications with KingMed. In addition, KingMed assigned a point pathologist on their side who is fluent in English."

As it would be with any telepathology program, IT issues were a challenge for UPMC's pathologists. "The main issue was slow Internet connectivity, which impacted viewing of whole slide images. To overcome this problem we now copy image files from China by transmitting them using high-speed image transfer software (called **Aspera**) to our own server in Pittsburgh," he added.

"Also, the initial image viewer we built relied on Java. Since Java constantly pushes out updates (which means our users need to keep accepting them), we built a vendor neutral HTML5 whole-slide imaging viewer that our pathologists can use as an alternative.

Communication Hurdles

"Another challenge was communicating with clinicians halfway around the world when we identified a need for more clinical information, missing gross descriptions, or when KingMed sent insufficient tissue for evaluation. To solve this problem, we incorporated functionality into our telepathology system that allows UPMC consultants to communicate directly via synchronous back-and-forth chat and email with KingMed pathology," he said.

"In addition, we keep the email trail within the system as part of working up a case, so that it is not lost," he added.

"Despite these hurdles, the program was profitable," he said. "But it took about two and a half years to recoup the hardware, software, and legal investment UPMC made.

For China Project, UPMC Had a Key Resource: A Pathologist with Strong Connections to China

WHENEVER A LAB EMBARKS on an international venture, overcoming language and cultural barriers could be a significant problem. For its partnership with KingMed Diagnostics, the Pathology Department at the University of Pittsburgh Medical Center had a ready solution.

"The most important factor in our success was having a champion pathologist in Chengquan Zhao, MD, a Professor of Pathology here at UPMC. Dr. Zhao is very famous in China, and has been instrumental to the success of our program for many reasons," said Liron Pantanowitz, MD.

Zhao is a guest professor at six universities or large hospitals in China and was the lead author of the article on the UPMC-KingMed partnership in the *Journal of Pathology Informatics* in November.

"I visited KingMed at least twice," Zhao said. "Also, I do the slide teaching, lecturing, and lead the discussions about the consultation cases. We also provide the opportunity for KingMed pathologists to learn pathology in our department here in Pittsburgh, and for KingMed's surgical pathologists in China we provide education based on the consultation cases.

"In addition, I am doing cooperative research with KingMed pathologists and mainly direct them for the clinical research. Since last year, six papers have been published in the main American pathology or cytopathology journals. Several other UPMC pathologists are also involved in these research activities," he added. "We find that good academic relations can enhance the telepathology relationship.

"For several years, the UPMC Pathology Department has built an academic relationship with the pathologists at the **301 Military Hospital**, one of the largest hospitals in China," added Zhao. "In addition, we've had two national cooperative pathology conferences in Beijing, including lectures by several UPMC pathologists."

"For other clinical labs embarking on this journey, I would say they need to understand that it is critical to have a dedicated pathologist liaison such as Dr. Zhao who is well respected, trusted, and understands both languages and cultures," he added.

"As you might assume, a joint venture like this also requires strong commitment from leadership on both sides, to get it started and to sustain it. For that, we credit the visionary nature of our senior pathology faculty, including Michalopoulus and Samuel A. Yousem, MD, and the KingMed leadership as well," Pantanowitz added. Yousem is the E. Leon Barnes Professor of Anatomic Pathology, Vice Chairman of Anatomic Pathology Services at UPMC, Director of the Division of Anatomic Pathology, and Co-Director of the Community Pathology Division.

"And, for any venture like this, you will need in-house IT expertise. We feel that our international telepathology program is a win-win endeavor. As indicated by the results in our paper published in the *Journal of Pathology Informatics*, international telepathology consultation improves patient care by facilitating access to pathology expertise. We also provide added value in our reports, by including prognostic information and treatment suggestions when appropriate. Finally, our good relationship with KingMed also has provided indirect benefits, such as education and academic collaboration," he concluded. **TDR**

—Joseph Burns

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UnitedHealth Warns Labs Not to Waive Patient Fees

➤Insurer says routinely waiving such fees may violate federal law, lead to state fraud inquests

➤➤CEO SUMMARY: UnitedHealthcare directly tackled the issue of out-of-network labs waiving or capping copayments, coinsurance and deductibles that are to be paid by patients. In a network bulletin this month, UHC said that such arrangements may violate federal law and could lead to state insurance department investigations into false claims. In the same bulletin to physicians and other providers, UnitedHealthcare also said it would require prior authorization for all genetic tests beginning later this year.

IN ITS LATEST NETWORK BULLETIN, **UnitedHealthcare** warned out-of-network laboratories not to waive or cap patients' copayments or deductibles. In the same bulletin, it also announced that it will require prior authorization for all genetic tests later this year.

In a bulletin to providers March 1, UHC says: "Effective Q3 2016, UnitedHealthcare will require care providers to obtain prior authorization for genetic testing for our commercial members. Details on how to request prior authorization, the genetic testing policy to be used in the review process, and other information will be included in a future Network Bulletin newsletter and on our physician portal."

On the issue of waiving patients' fees, UHC is specific and threatening. "Some nonparticipating labs attempt to attract customers by waiving or capping copayments, coinsurance or deductibles. Such arrangements undermine the benefit plan by eliminating incentives created to encourage members to choose to receive care within the network and to discourage overutilization of services," says UHC, the nation's largest health insurer.

"UnitedHealthcare's benefit contracts exclude coverage for any out-of-network lab services for which the provider waives the coinsurance, copayments, or deductibles. In addition, routine waiver of coinsurance, copayments, or deductibles may be a violation of the federal False Claims Act, subject to investigation by the Office of the Inspector General and/or any applicable state insurance department's fraud division," wrote UHC.

➤Referrals To Network Labs

The bulletin also explains that UHC's network includes "more than 1,500 clinical reference laboratories." In-network physicians and other providers, "are expected to refer our members to network laboratories for clinical lab and anatomic pathology, unless otherwise authorized by UnitedHealthcare consistent with their participation agreement," the bulletin says.

UnitedHealthcare officials did not respond to a request for comment.

The warning about waiving patients' payments is likely a result of leaving so many laboratories out of its network, stated Linda D. Liston, CPC, Director of Managed Care Services for **McKesson Business Performance Services**.

"UnitedHealthcare gets a lot of out-of-network charges because it won't give small, local, or regional labs contracts. We know this from our experience with UHC," she explained.

"When we tell UHC that it is receiving a large number of lab test claims for UHC members in a particular area and that is a reason why it should contract with those local or regional labs, its officials say, 'We've got our national agreement and don't need another lab or pathology group," explained Liston, who has served as McKesson's director of managed care services for 20 years.

Battle To Get Lab Contracts

"With UHC, it's a constant battle to get contracts," she added. "But UHC is not alone," she continued. "Some insurers say that, if out-of-network labs waive patients' co-insurance or deductibles, they drop the allowable charge by 20%.

"We also see health insurers write into their commercial contracts that labs cannot waive the 10% or 20% co-insurance payments that patients are required to pay," she said. "But waiving of copayments is not the only problem UHC has with out-of-network labs.

"We speak with UHC almost every day about our lab clients," noted Liston. "If a lab client needs a contract, we explain how—when UHC has an in-network hospital—it needs to have an in-network lab too. Otherwise, UHC members will expect in-network prices for lab work but get hit with out-of-network charges. Even after we explain that, it often takes UHC many months to years to get a contract implemented.

"Here's an example," she said. "We work with many independent labs that provide laboratory services for local hospitals because hospitals outsource that lab work. For any hospital lab that doesn't have a histology section, then the inde-

Gene Test Pre-Approval Coming to UnitedHealth

AS CLINICAL LABORATORIES KNOW, most health insurers have limited coverage for genetic tests. But each payer seems to adopt its own approach.

"You have different payers doing different things in how they cover genetic tests," observed Linda D. Liston, Director of Managed Care Services for McKesson Business Performance Services.

In its network bulletin dated March 1, 2016, UnitedHealthcare plans to adopt its own solution to coverage by requiring prior authorization for genetic tests beginning in the third quarter. UHC says it will explain the prior-authorization process sometime in the coming months.

"By requiring prior authorization now, United Healthcare is coming rather late to the game," noted Liston. "Other insurers already have these processes in their plans. Some lab professionals speculate that this policy statement makes it appear that UHC is taking a step that they think will help drive their lab business to what they consider their preferred or participating labs.

"UnitedHealthcare is like every other insurer, trying to control costs and steer their patients to in-network or participating labs," she stated. "The question now is whether they will use a system like **Laboratory Corporation of America's** Beacon Laboratory Benefit Services—which they have in Florida—in other states."

BeaconLBS is a clinical decision support system that physicians are required to use for pre-notification and prior authorization for some 80 laboratory tests for UnitedHealthcare's commercial HMO patients in Florida. *(See TDR, July 21, 2014.)*

pendent lab does the technical component (TC) and bills for that service. But if that independent lab is out of network, then the patient gets hit with a higher deductible and coinsurance.

In-Network Pricing

"Also, the pathologist bills for the professional component (PC) and that pathologist or pathology group also needs to be in-network for the UHC patient to get in-network pricing for all the services provided in that episode of care," she added.

"Most of the time we see a pathology group practice doing the PC, but the hospital's lab is responsible for the TC," explained Liston. "Thus, how does the pathology group get paid by commercial insurers? It needs a contract to be a member of the payer's network for the services it provides to the hospital's inpatients.

"But then UHC—and other health insurers too—will say, 'It's not that big of a deal.' In fact, yes, it is a big deal," Liston said. "Insurers need to realize that any of their patients in this situation will get an in-network bill for the technical component (TC) service performed by the hospital's histology lab, but an out-of-network bill for the professional component (PC) that is performed by the pathology group.

TC/PC Baffles Insurers

"In these situations, UHC tells us, 'We have a national lab and can outsource the technical component,'" she added. "But in this instance, we're talking about inpatient services. How does UnitedHealth outsource hospital inpatient work to a national lab? UHC's staff needs to understand how their policies can affect their beneficiaries negatively.

"These are the reasons why it is logical to believe UnitedHealthcare continues to have a lot of lab leakage," surmised Liston. "We see labs and pathology groups across the country that are out-of-network, yet they have a significant payer mix—including work from UHC. It may not be 50% of their volume, but it could be 10% to 15% of their payer mix.

"The bottom line is UHC—and other insurers—should have more in-network labs where they need them most, concluded Liston. TDR

—Joseph Burns

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Waiving Lab Patient Fees Invites Payer Audits, Suits

IN RECENT YEARS, private health insurers and federal healthcare prosecutors have begun to pay attention to the business practices of some lab companies soliciting physician lab test referrals while promising to never bill their patients for the co-pays, out-of-pocket, or deductible amounts required by their health plan coverage.

The practice of waiving patient fees has been an issue in several recent high-profile federal whistleblower cases where settlements were announced. One such case involved **Health Diagnostics Laboratories, Inc.**, and **Singulex, Inc.**, and the settlement was announced on April 9, 2014. Both labs settled while denying the charges. *(See TDR, April 20, 2015.)* Another federal settlement involved **Millennium Healthcare**, a toxicology and pain management testing company. This settlement was announced on October 19, 2016, and Millennium denied the charges. *(See TDR, November 16, 2015.)*

Last year, **Aetna, Inc.**, and **Cigna** filed lawsuits against Health Diagnostics Laboratory, claiming that HDL did not bill patients for their share of the lab test fees and seeking tens of millions of dollars.

Also, during 2015, THE DARK REPORT was first to publicly alert clients and readers that some health insurers, when auditing laboratories, were now seeking documentation that, for the lab test claims being audited, the laboratory had billed patients for the required copays and deductibles. *(See TDR, August 25, 2015.)*

Regulatory Update

FDA Steps Up Test Enforcement, Saying Tests Need Clearance

THIS MONTH, AT LEAST THREE CLINICAL LABORATORY DIRECTORS got letters from the **Food and Drug Administration** raising questions about assays for the Zika virus.

The letters say the tests appear to meet the FDA's definition of a medical device and thus are subject to premarket clearance, approval, or Emergency Use Authorization. In the letters sent to two hospitals in Houston and to **MD Biosciences** in Minneapolis, FDA requested additional information within seven days, and the three labs said they would comply.

While these letters were news last week, they represent the FDA's continuing efforts to crack down on how clinical laboratories offer laboratory-developed tests (LDTs) for clinical purposes or to consumers. Last fall, seven clinical labs received letters from the FDA, according to *Regulatory Focus,* a publication of the **Regulatory Affairs Professional Society**.

In December, the FDA sent letters to **Genomic Express** and **Healthspek** about marketing direct-to-consumer pharmacogenetics tests, saying that three tests from Genomic Express and one from Healthspek are medical devices that the FDA must clear before marketing. Two years ago, FDA proposed to oversee the approval of lab-developed tests and last year, FDA officials said they were taking steps to oversee these tests this year.

Between September and early December, the FDA sent similar letters to five clinical lab companies: **Pathway Genomics**, **DNA4Life**, **DNA-Cardio-Check**, **Interleukin Genetics**, and **Harmonyx**, RF reported.

In letters dated March 2, FDA Deputy Director James Woods wrote to James Musser, MD, PhD, Professor of Pathology and Genomic Medicine at the Institute for Academic Medicine at **Houston Methodist Hospital**, and to James Versalovic, MD, PhD, Pathologist-in-Chief at **Texas Children's Hospital**. In the letters, Woods wrote that, as a result of the FDA's review of the labs' promotional materials, "we believe you are offering a high-risk test that has not been the subject of premarket clearance, approval or Emergency Use Authorization."

New Lab Tests For Zika Virus

The *Houston Chronicle* reported that in February, the hospitals announced the development of a test to detect genetic material from the Zika virus within seven days of the onset of symptoms and would use it only for patients in their hospital systems. Test results are available in a day, the newspaper reported.

On March 4, Woods sent a similar letter to Eddie Moradian, PhD, CEO of MD Biosciences, about MDB's Zika Virus. In the three letters regarding Zika tests, Woods requested more information.

In response to the FDA's letters, the **Association for Molecular Pathology** said on March 14 that it was 'very concerned and disappointed to see the FDA taking enforcement action" against the Houston hospitals. "Given the ongoing outbreak of the infection and risk of infection in the Houston area, these types of tests are critical for patient care and should be made available to these patients in need," AMP said. **TDR**

—Joseph Burns

Lab CEO Sees Three Trends Cutting Volume, Revenue

➤Clinical lab testing industry being reshaped by major changes in healthcare and lab market

➤➤CEO SUMMARY: Following the sale of his hospital lab outreach business to a national lab company, former CEO James Fantus told THE DARK REPORT about the significant trends he saw unfolding in the Northeast. They include: a shrinking number of physician customers for labs; a rising number of patients with high-deductible health plans, resulting in lower lab test utilization; and increased competition from national labs that force regional labs to match the large labs' prices just to remain in contention for hospital and health plan contracts.

AT THE END OF FEBRUARY, the acquisition of **Clinical Laboratory Partners** of Newington, Conn., was completed by **Quest Diagnostics Incorporated**. Formerly owned by **Hartford Healthcare** and founded in 1998, CLP has been one of the most successful hospital lab outreach businesses in the United States.

For more than a decade, James Fantus served as President and CEO of Clinical Laboratory Partners. Prior to his arrival at CLP, Fantus had several decades of experience leading a number of outreach lab organizations owned by hospitals and health systems.

Consequently, Fantus is among a handful of lab industry executives serving today whose experience reaches from the era of "any willing provider" and "usual and customary fees" of the 1980s right up to the current era of ACOs, integrated clinical care, and precision medicine. This experience gives Fantus a unique perspective on what is truly different in today's lab testing market, particularly when assessed against the evolving healthcare trends he dealt with at CLP.

To learn Fantus' view on the current viability of hospital laboratory outreach programs, THE DARK REPORT asked him to discuss his insights and recommendations about strategies and actions labs should employ to add value. This is part one of a two-part series.

"Since 2010—about the time that the Affordable Care Act became law—wave after wave of changes have rolled over the clinical lab industry," stated Fantus. "These changes include sharply declining payments, narrow networks, and fewer opportunities for growth.

➤A Big Share of Trouble

"Certainly other healthcare providers have experienced many of these same problems, but clinical labs seem to have borne a disproportionate share of trouble," noted Fantus. "I consider three developments to be most significant for clinical labs.

"First is a shrinking number of physician customers for labs," he said. "Second

is the rising number of patients with high-deductible health plans, resulting in lower test utilization.

"Third, increased competition from large national labs forces regional labs to match the large labs' prices just to remain in contention for hospital and health plan contracts," stated Fantus.

For Fantus, regional labs still have several ways to compete effectively and prosper in the current marketplace. "One effective business strategy is to partner or collaborate with large regional health system networks that are aggressive at acquiring and retaining market share," suggested Fantus. "However, labs must first address several specific challenges.

"The biggest challenge is probably the most profound one and that is, we are running out of customers," declared Fantus. "That was one factor that prompted the sale of CLP to Quest.

"Our physician customers are already aligned with a hospital or health system," he said. "And, many physicians are selling their practices to health systems or joining bigger practices. Combined, just those two factors mean there are fewer independent doctors for our sales staff to call on.

"The way health systems operate here in Connecticut is probably similar to the way they operate in other states, meaning they're all aggressively competing against each other. They rarely cooperate to any degree and don't want to," he added.

"That means our lab serves the client base we have, but once you get away from those physicians, it's very hard to pull any of them away from the other health systems," Fantus commented. "So, for me, the biggest change I've seen in the past five to six years has been the disappearing, private practicing physician.

"The other challenge labs face is one we've seen coming for years: the effect of high-deductible health plans," he added. "To bring down the cost of healthcare, many employers and health plans are making patients pay for part of it. The effect is lower utilization of healthcare services—not just for lab tests but for all the other clinical services offered by a health system.

"Now you have a one-two combination of disappearing physician customers and the remaining lab clients ordering fewer tests," stated Fantus. "As a clinical lab, you can reduce your costs only so much. If a patient asks that two or three tests be dropped out of an order, the lab must still perform those one or two tests that remain.

"Costs to operate your patient service centers remain; you still have phlebotomy costs; and all the normal costs of doing business are still present," he noted. "That is why the reduced number of specimens means it's tougher and tougher to make the operating margins we once did.

Payers Are Cutting Costs

"When specimen volume declines, a lab's cost-per-test rises. It's simple economics," said Fantus. "Unfortunately, these two trends are widespread now. They are the key negative drivers affecting the lab outreach business, at least here in Connecticut. Most labs cannot do anything about these trends.

"At the same time, payers are trying to reduce their costs and are asking labs to get their costs in line with those of the large national laboratories," he explained. "Payers know they can switch to Quest or **LabCorp** if needed.

"But some payers may not want to make that switch because they have solid relationships with local and regional labs," continued Fantus. "So if the costs for a lab like CLP are much higher than those of Quest or LabCorp, then that could be a problem. At the very least, it means payers can threaten our lab to get our costs in line by telling us that we will see no further increases in our rates until our fee is equal that of the national labs.

"As a result, CLP was not seeing annual rate increases as we did in years past," he added. "In the last two years, CLP held the line on its reimbursement rate because

Health Insurers in Connecticut Are Not Yet Embracing New Payer Reimbursement Models

DESPITE THE MOVE AMONG health plans to adopt risk-sharing contracts, health insurers in Connecticut have been reluctant to move away from fee-for-service payment, at least for now, stated James Fantus, former President and CEO of Clinical Laboratory Partners.

"Payers here seem to be resisting alternative forms of payment," he explained. "CLP asked for at-risk contracts, but so far payers have refused to do it.

"It may seem counter-intuitive, but I think the reasons are obvious: Health plans don't want us to become like an insurance company. That's their job and they don't want to give it up," he opined.

"If a provider like Hartford Health is managing the entire continuum of care, then what role is left for the insurance company?" Fantus asked. "Why do we even need health insurers?

"Despite all the talk about accountable care organizations and risk-sharing contracts, there's conflict across the country. Health insurers do not want another **Kaiser Permanente** to develop," he said.

"If other health systems in Connecticut developed ACOs, these ACOS would cut out the middleman—the health insurance company—which means ACOs would deliver lower cost care," he said. "That may be why we have not seen the development of ACOs here in Connecticut. That, plus the big insurers here—**Aetna** and **Cigna**—want to manage the care for their own employees.

"This could be the next big battle in the development of ACOs and how care gets paid for," he continued. "In fact, in our market, we've seen capitation go away over the past couple of years. About 20 years ago, 35 hospitals banded together in an organization called the **Connecticut Hospital Lab Network**. All the hospital labs in our state participated, except four.

"This was when Quest was getting all the capitated contracts here," he recounted. "The consortium's sole purpose was to go to the payers as a single contracting entity and it worked!" recalled Fantus. "Through this consortium, the hospital labs eventually won all the capitated contracts.

"But since then, capitated contracts have been disappearing," he noted. "Here in Hartford, we're down to only two capitated contracts. Last year there were three. One was with **Anthem**, one was with **Connecticut Care**, and one was with **Oxford**. Then Anthem got out of its capitated program.

"In five years or so, we've seen enrollment in capitated contracts go from hundreds of thousands of members down to the tens of thousands. It could be that capitated contracts don't work well with high-deductible health plans and HDHPs could make capitation unnecessary," he concluded. "Just look at all the HDHP plans the insurance exchanges offer. That's what insurance will look like in the coming years," he predicted.

health plans have a strong emphasis on reducing what they want to pay.

"With those three big trends, how does a lab like CLP overcome negative factors like these?" he asked. "This challenge is more difficult if the parent company faces many of the same problems. Cash is short and the health system wants to cut costs and make changes for the future.

"CLP's parent company, Hartford Health Care, is like many others in that it has seen patients moving away from inpatient care to outpatient settings for at least the past 20 years," Fantus explained. "That means their revenue is declining too."

In part two of this two-part series, James Fantus discusses the lab's opportunity to contribute value through integration of healthcare data. **TDR**

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Tougher times in the clinical lab testing market have claimed another lab company. On February 28, **Artherotech, Inc.**, posted a notice on its website stating that it had closed permanently, as of that date. Along with its several hundred employees, Artherotech's closure caught many lab executives by surprise. Founded in 1994, during the heyday of closed-panel HMOs, the Birmingham, Alabama-based lab company had weathered more than two decades of tough market conditions. On its website, Artherotech stated that the closure "resulted from adverse changes in the regulatory environment, increased pressure from commercial insurance payers, and continued compression of profit margins."

MORE ON: *Artherotech*

Artherotech's cholesterol test, the VAP+ Lipid Panel, was generally considered to be a successful assay. In 2011, Artherotech was acquired by **Berman Capital**, a private equity company that had previously held ownership positions in such lab companies as **Esoterix, Inc.**, and **Athena Diagnostics**. Financial analyst Dan Primack wrote that, at the time Berman Capital bought Atherotech, it had annual revenue of $30 million. That increased to $120 million within a few years. There may not be much for a Chapter 7 bankruptcy, as Primack noted that Artherotech's proprietary cholesterol test is licensed from the **University of Alabama**. In a bankruptcy action, that license would revert back the university.

LIFE LABS TO CLOSE 15 PATIENT CENTERS

In the Province of Ontario, Canada, **LifeLabs** announced that it would close 15 patient service centers and reduce hours at 53 other collection sites. Company officials said it was an "effort to cope with mounting costs, cutbacks in government funds, and a higher volume of patients."

TRANSITIONS

- Gregory D. Clark, PhD, is the new President and CEO of **LABS, Inc.**, of Centennial, Colorado. Clark has held executive positions at **PAML**, **Baylor Healthcare System**, **Westcliff Medical Labs**, **Oregon Medical Labs**, and also at **Quest Diagnostics Incorporated**.

- **Laboratory Alliance of Central New York, LLC**, of Syracuse, New York, named Michael W. Graber, MD, as its new Medical Director. Graber is currently employed by **Onandaga Hill Pathology PC**, and is a staff pathologist at **Upstate University Hospital**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 11, 2016.

SPECIAL SESSION!

Using Lab Test Data to Add Value for Physicians, Patients and Payers

Bill Baker

Chief Information Officer, Tricore Reference Lab

TriCore's Early Successes at Advancing Clinical Care and Improving Patient Outcomes with Enriched Clinical Intelligence

In a world of healthcare big data and population management, can a laboratory transform itself into a "Diagnostic Health Exchange?" That is the strategy at Tricore Reference Laboratories in Albuquerque, New Mexico.

Bill Baker will advance the Tricore story, sharing current success. It was at last year's *Executive War College* when Tricore CEO Khosrow Shotobani captured the audience by demonstrating how Tricore was already combining lab test data with other clinical data sets to deliver early alerts to physicians about which respiratory diseases were showing up in their communities and how Tricore was helping payers identify new beneficiaries with chronic conditions that might otherwise go undiagnosed or untreated.

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