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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

Damon Laboratories, Mitt Romney, and Politics

IT IS SELDOM THAT THE CLINICAL LABORATORY INDUSTRY HITS THE RADAR SCREEN during a presidential election. So it is with some interest that I report to you that Mitt Romney recently touted the lessons he learned while serving on the board of **Damon Clinical Laboratories, Inc.**, as useful for guiding the nation.

Romney, now the Republican Party's official candidate for President, wrote an opinion piece for *The Wall Street Journal* that was published on August 23. It was titled "Mitt Romney: What I Learned at Bain Capital." The paragraphs of most interest to pathologists and laboratory executives are these:

> *Running a business also brings lessons in tackling challenges. I was on the board of a medical diagnostic laboratory company, Damon, when a competitor announced that it had settled with the government over a charge of fraudulent Medicare billing. I and fellow Damon outside board members joined together and immediately hired an independent law firm to examine Damon's own practices.*
>
> *The investigation revealed a need to make some changes, which we did. The company, along with several other clinical laboratory companies, ended up being fined for billing practices. And a Damon manager who was responsible for the fraud went to jail. The experience taught me that when you see a problem, run toward it or it will only get worse.*

It was 1990 when Bain Capital made an investment in Damon. The $111 million settlement between the federal government and **National Health Laboratories, Inc.** (NHL), was announced in 1992. Damon was sold to **MetPath, Inc.,** (now **Quest Diagnostics Incorporated**) the following year. It was in 1996 when the Damon case was settled for a total of $119 million in civil and criminal penalties.

The 1990s were the days of the Department of Justice's LabScam campaign that netted more than $1 billion in penalties and civil settlements from both independent clinical labs and hospital labs. It is fascinating to learn that Mitt Romney was serving as a director for a public laboratory company during the time when the 1992 settlement with NHL unleashed federal prosecutors on the lab testing industry. A wider question for Mr. Romney is this: Did he learn how the complexity of federal Medicare and Medicaid regulations—along with uneven enforcement of the law—can make any healthcare provider a law-breaker on any given day, almost at the whim of a federal regulator? TDR

Prostate Biopsy Claims Affected by Policy Change

Medicare carrier for region J1 and region J11 first to adopt an update published by NCCI

CEO SUMMARY: Quietly, with no fanfare and little advance public notice, the Medicare program is taking steps to change reimbursement policy for prostate biopsies. On August 7, 2012, Palmetto GBA adopted the new policy published on January 1, 2012, by the National Correct Coding Initiative (NCCI). Pathology billing experts and attorneys state that this policy limits reimbursement to four units of service per case. The news is only now reaching pathology labs across the nation.

BAD NEWS LIES AHEAD for anatomic pathology laboratories that perform large volumes of prostate biopsy testing. Payers may be poised to institute deep reimbursement cuts for 12-core prostate biopsy claims.

If this happens, it will greatly reduce the revenue flowing to those pathology laboratories now testing large volumes of prostate biopsies. What makes this threat credible is that the first payer known to take steps to reduce reimbursement for prostate cancer biopsy testing is **Palmetto GBA**, one of the nation's largest Medicare carriers.

On January 1, 2012, the National Correct Coding Initiative (NCCI) manual was released, and it referenced reimbursement for prostate biopsies. In this release, NCCI was attempting to distinguish between the appropriate use of HCPCS G0416-G0419 (known as G codes) and CPT 88305, according to **PSAPath, LLC**, a lab billing company in Florence, South Carolina.

In a note it recently sent to its client labs, PSAPath said, "The NCCI manual included ambiguous language which many understood to be another attempt by Medicare to distinguish between the appropriate use of the HCPCS G0416-G0419 codes introduced in 2009 for prostate biopsy specimens collected via the transperineal or 'saturation' biopsy technique (PSB) and the use of CPT 88305 for reporting prostate needle biopsies collected via the traditional transrectal ultrasound (TRUS) technique.

"However, a policy update published by Palmetto GBA [on August 7] has shed new light on the curious NCCI language,

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making it clear that it is Medicare's intent to require the use of these new G-codes for all prostate procedures anytime five or more separate specimens [per case] are billed," PSAPath said. "This new policy effectively caps reimbursement for all prostate biopsy specimens, irrespective of the manner in which they were collected."

Jane Pine Wood, attorney at **McDonald Hopkins**, the national law firm based in Cleveland, Ohio, sent a note to clients of her law practice. Wood wrote that "On August 7, 2012, Palmetto GBA, a Medicare contractor, issued a policy update entitled 'Prostate Biopsy Coding/ Billing Guidelines.' This Palmetto policy references a National Correct Coding Initiative (NCCI) update that was published in January 2012, and appears to be the first instance of a Medicare contractor confirming its adoption of the January 2012 NCCI update."

The issue of concern to anatomic pathology groups and pathology laboratory companies is how the new policy will change the way prostate biopsy claims for Medicare patients can be submitted to Palmetto GBA. Wood wrote that "...The August 7, 2012 Palmetto GBA policy adopts the NCCI update, explaining that the number of prostate biopsy specimens (regardless of collection technique) that can be reported with CPT Code 88305 is limited to four units per case, and the evaluation of five or more prostate biopsies must be reported using the G codes."

Palmetto Posted The Policy

On the Palmetto GBA website for Medicare region J1 (covering the states of California, Nevada, and Hawaii) and J11 (covering the states of North Carolina, South Carolina, Virginia, and West Virginia), the updated policy for prostate biopsies is presented. It states, in part, that:

Effective January 1, 2012, Medicare has limited the number of prostate biopsies that may be reported for CPT© code 88305 to four (4) services. To report five or more prostate biopsies, providers must use G0416 with 1 unit of service. NOTE: Report ONLY CPT code 88305 or HCPCS code G0416 for the prostate biopsies based on the number of biopsies performed.

This is a significant development for all laboratories that perform substantial numbers of prostate biopsies. It will effectively lower the reimbursement currently paid for a 12-core prostate biopsy.

Financial Ramifications

PSAPath explained the financial implications of the change as follows:

The Medicare Physician Fee Schedule National Payment Amount (unadjusted for locality) for G0416 is $670.88, which represents the equivalent of 6.34 units of 88305 (which has a National Payment Amount of $105.86 per unit). Unfortunately, for those who perform PC-only services, the news is worse still. The National Payment Amount for G0416-26 is $182.10, which represents the equivalent of only 5.0 units of 88305-26, which has a National Payment Amount of $36.08 per unit.

Therefore, laboratories and physician practices that typically bill for more than six specimens for a prostate biopsy case will see their reimbursement for these cases capped at the equivalent of 6.34 units for a global service and 5.0 units for a PC-only service. For a laboratory or pathology practice that has typically billed for 12 specimens for the average prostate case, the Medicare reimbursement will effectively be reduced by 47% on global cases and by 58% for PC-only cases.

THE DARK REPORT is one of the first to report these developments. At this point, Palmetto GBA is referring all questions to the **Centers for Medicare and Medicaid Services** (CMS). Because of the new policy's expected financial impact, there is likely to be quite an uproar from many pathology laboratories. TDR

—Joseph Burns

Root Cause Analysis Used To Find Source of Errors

After validation of new chemistry analyzer, random errors trigger letters to 1,000 patients

CEO SUMMARY: It is a reminder that today's sophisticated laboratory test systems still have the potential to malfunction in unexpected ways. This spring, following installation and validation of a new chemistry instrument, one Canadian hospital laboratory quickly recognized that a series of random errors were a sign that the instrument had issues—but not before specimens from 1,000 patients had been tested, requiring notification letters to be sent to these individuals.

ANYTHING CAN GO WRONG when installing a new lab analyzer. Hardware, software, or both can fail during the initial tests.

Recently, one Canadian hospital laboratory sent letters to 1,000 patients suggesting they should consult with their physicians about the need for retesting. This step was taken after it was determined that a new chemistry analyzer was producing lab test results that could be inaccurate.

The patient notification program was carried out because of concern about test accuracy for specimens run between May 28 and June 6 on the new lab analyzer. The episode is a reminder to all clinical laboratories that, because of the increased volume of patient testing, any small problems or glitches with laboratory testing instruments have the potential to quickly affect a significant number of patients.

Further, the root cause of the problem demonstrates how the complex technologies that come together in today's state-of-the art diagnostic instrument systems can often generate problems that are a challenge for the typical lab's QA/QC program to identify and resolve.

"This story begins on April 23," stated Shane Buchanan, who is Lab Manager at 106-bed **Colchester Regional Hospital** in Truro, Nova Scotia. "That is the day when the manufacturer delivered a new analyzer to measure blood glucose, creatinine, calcium, and other biochemical analytes.

New Laboratory Analyzer

"With the manufacturer's technician on site, we began to test the instrument and validate the assays," he continued. "After the analyzer was moved from the area where it was validated to the actual laboratory and patient testing was initiated, we had a small number of infrequent and random errors in our quality control (QC) testing. The fact that the errors were infrequent and so random made identifying the cause extremely challenging." Buchanan did not want to identify the vendor.

"Each time we had an erroneous QC result, we re-ran our QC samples through the system and each time they checked out fine," recalled Buchanan. "Based on the accurate QC procedures and upon consultation with the technical representative from the vendor, we attributed such prob-

lems as part of the normal growing pains involved with the set-up of a new analyzer.

"These errors were so random that even the vendor had trouble identifying the cause," he added. "We transitioned from running 25 samples per day during validation to our full production runs of 200 to 400 live patient samples per day.

"The first time an abnormal result was seen in a patient sample was June 4th," he said. "The abnormal tests were rerun on another analyzer and manual delta checks were performed on seemingly abnormal patients. The vendor was contacted and this was again attributed to 'growing pains.'

"Minimal testing was performed on the analyzer on June 5th," noted Buchanan. "By June 6th, we determined that the best resolution was to take this instrument out of service. We wanted to err on the side of patient safety and we had a second analyzer available. This is when we sent letters to patients informing them about the situation and the possible need for retesting.

Taken Out Of Service

"Once the analyzer went out of service, we identified the source of the problem," noted Buchanan. "The machine forms its own cuvettes with two sets of film. One track carries the front film and one track carries the back. After the films fuse together, hot air is blown in to form a 'bubble' which is the cuvette.

"The glitch occurred when consecutive tests were run," he continued. "If one test had a high volume of reagent, the reagent would overflow into the adjoining cuvette and affect the test results in that adjoining sample. But it wouldn't happen every time and it happened only when the reagent reached a certain level.

"The root cause turned out to be a locking screw that was not secured properly on the cuvette assembly mechanism during a routine service call performed by the vendor," Buchanan said. "The vendor indicated that this error had occurred in only one other analyzer in almost 10 years. This was the cause of that small and random error leading to the inaccurate results."

The experience of Colchester Regional Hospital's lab is a reminder that sophisticated analyzers can still malfunction in unexpected ways—and when they do, large numbers of patients can be affected. TDR

—By Joseph Burns

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Lessons Learned in Set-up Of New Chemistry Analyzer

FOR LAB MANAGER SHANE BUCHANAN, five important lessons were learned from the experience this spring when random errors began appearing following the installation of a new chemistry analyzer.

"First, it helps to be judicial in following all quality control (QC) steps, as our lab staff was doing," stated Buchanan. "Second, we are working with the vendor and other laboratories to establish delta check limits, a capability that exists in our laboratory information system. Not every hospital lab runs them.

"Delta checks are one way to rule out mislabeling, clerical errors, or possible analytical errors," he said. "Running them may have helped us to more quickly find the source of the errors with our new analyzer.

"Third, we consolidated all of our log books," stated Buchanan. "Previously, we had one log for QC problems and one log for troubleshooting. Now, all these communications go into a single logbook.

"Fourth, we asked the vendor to work with us to improve our QC education, troubleshooting, and documentation," he added.

"Fifth, our chemistry staff took this incident to heart," concluded Buchanan. "Many of them felt bad about it. We emphasized that this was a random error and that they had done the right thing at every step. Because of how these incidents can affect patients, it caused our lab staff to redouble efforts to ensure errors don't happen."

Dark Index

Narrower Provider Networks Topic during Quest Conference

LabCorp discusses different healthcare trends and emphasizes its advances in informatics

SINCE MAY 1, 2012, the nation's largest clinical laboratory company has had a new CEO, who is Stephen H. Rusckowski. The company's second quarter conference call provided an opportunity to learn more about how he views **Quest Diagnostics Incorporated**.

Conducted on July 19, the first topic of the call was the financial report. For Q2-12, revenues at Quest Diagnostics were essentially flat, at $1.907 billion compared to $1.903 billion for the same quarter 2011. Clinical testing revenues at Quest Diagnostics were up 0.7% for Q2-12. The number of requisitions was also up .07% for the quarter and revenue per requisition was unchanged, compared to Q2-11.

Growth Strategies

Rusckowski was quick to acknowledge the flat rate of growth at Quest Diagnostics. "We are being thoughtful and disciplined in developing our plan to restore top line growth and improve shareholder returns," he stated, adding that more detailed growth plans would be shared in the fall, following "a thorough review of our businesses and operations as part of this process."

To support growth, he told analysts on the call that the company was evaluating its selling and marketing efforts, as well as looking for ways to improve the way it brings diagnostic innovations to market. "We do have some good examples of what we need to replicate to grow this business," Rusckowski said.

In the short term, one major emphasis is to continue the major cost reduction program that was instituted by Quest Diagnostics' former CEO. It was launched with the goal of eliminating $500 million in costs from the company by 2014. This program is still in place. It is now called "Invigorate," and "is a top priority for me," stated Rusckowski. "From my first week on the job, I've been personally involved in Invigorate. I am personally chairing this effort.

"I've met with the teams focused on the biggest priority, the areas like lab operations, procurement, general administration, IT, to name a few," he continued. "Each of these teams are required to manage their projects with structured, disciplined, and rigorous program management approaches.

"I am assuring that proper resources are properly deployed to these efforts," stated Rusckowski. "Finally, I am challenging the teams to look for additional opportunities and to accelerate the pace at which we implement the Invigorate program."

Continuous Improvement

It is likely that the principles of Lean, Six Sigma, and process improvement figure prominently in this effort. It was back in the late 1990s when Quest's then-CEO, Kenneth Freeman, instituted a broad productivity improvement program anchored in Six Sigma. Quest Diagnostics has a host of Six Sigma Black Belts and it

has had almost 15 years to nurture a corporate culture of process change and continuous improvement.

What will have broad interest for pathologists and lab administrators is how Quest Diagnostics wants to serve the managed care industry. The call with analysts focused on the mutual goals that health insurers and Quest Diagnostics have in narrowing provider networks.

Discussions With Payers

In meetings with payers, Rusckowski stated that discussions centered on the topics of quality and cost. Also discussed were integrated care models, like accountable care organizations (ACO), and how the Accountable Care Act (ACA) will increase the number of people with insurance.

Payers are preparing themselves for change, noted Rusckowski, who said that "in that context, they believe that they need to do a better job of working with us on narrowing their networks for what they would provide. So therefore, they hope to work more closely with us to make sure that we work together because we're both incentivized to do that."

The sustained pressure on pricing across the entire healthcare industry was acknowledged and attributed to such factors as rising costs, more chronic disease, and the aging population. "That price pressure will continue," predicted Rusckowski. "The question is how does that unfold and how does that relate to this market, specifically, with the changes that we see going forward?

"We see people [payers] wanting to narrow their networks," said Rusckowski in answer to his own question. "Therefore, there should be more consolidation in the volumes around fewer suppliers of laboratory testing services and that plays nicely into what we are all about and what this industry is all about.

"Second, as hospital systems acquire physician practices, they're looking at what they need to do," he added.

The same issues of ACOs and the ACA are topics in conversations Rusckowski is having with hospitals and health systems. He explained that hospitals are assessing what they might do with their laboratory operations "and they are starting to have more conversations with us in terms of how we can help them with laboratory management services, where we could potentially look at outsourcing, where we can look at reference testing," he noted.

In answer to an analyst's question on this point, Rusckowski answered. "We do have an opportunity... [to work] together with the health plans to get more volume and they see an opportunity in their cost structure—and we see an opportunity with our volumes—to do that with them."

Early Retirement Program

Another strategic initiative underway at Quest Diagnostics that will interest lab administrators is a voluntary early retirement program that will be offered to "certain qualified employees." Cost savings are estimated to be $40 million per year when implemented.

"The program will allow us to reduce the size of our workforce, reduce our average wage bill, and update the skills of the workforce," explained Rusckowski. One goal of the Voluntary Severance Program is to improve the productivity of Quest Diagnostics' labor force and he emphasized that point, noting "we are very, very tight on any hire we make and specifically looking for opportunities to drive productivity."

As all of these corporate initiatives illustrate, Quest Diagnostics explicitly recognizes that there will be ever-greater pressure on providers to reduce costs. To remain competitive with the national labs in coming years, local laboratories and hospital lab outreach programs will need to emphasize cost reduction within their own operations. For smaller labs to survive in downstream years, it will be necessary to operate with a much lower cost structure than they do today. TDR

LabCorp Executives Emphasize Different Priorities and Discuss Emerging Health Trends

DURING THEIR SECOND QUARTER CONFERENCE CALL with financial analysts, executives at **Laboratory Corporation of America** emphasized different factors in the lab testing marketplace than were discussed during the Quest Diagnostics conference call.

In their conference call, also conducted on July 19, executives at LabCorp first addressed the financial performance of their company. Revenue for second quarter was up 1.4%, at $1.423 billion versus $1.403 billion in Q2-11. Specimen volume was flat. Revenue per requisition increased 1.5%, compared to the same quarter in 2011.

Following the financial report, LabCorp executives detailed a rather lengthy list of achievements. CEO David P. King described some of the accomplishments of LabCorp's "Five Pillar" strategy. In the informatics realm, the numbers demonstrate the sizeable changes unfolding in how office-based physicians use information technology.

"We have added over 3,500 new client EMR interfaces year-to-date and are on pace to exceed 7,500 in 2012," stated King who added that the company's Beacon platform "is now deployed to more than 14,500 sites and has more than 66,000 users."

Patient Experience

One continuing theme at LabCorp are innovations designed to raise the competitive bar in the lab testing marketplace. King spoke to the patient experience, explaining that "we have expanded our patient self-service offerings through two key enhancements.

"First, our online appointment scheduling system now allows patients to enter demographic and insurance information," he said, "reducing their registration time at our PSCs and enhancing our efficiency and their experience. Second, in select markets, we have introduced the telephonic voice recognition system to schedule appointments in our patient service centers."

Local laboratories should take notice of how LabCorp is using informatics to "automate" many types of transactions with patients. Among other things, these features eliminate paper and reduce the time and labor required for LabCorp to serve a patient.

"We successfully completed the pilot of our Beacon patient portal," stated King. "The portal is a secure and easy-to-use online solution that enables patients to receive and share lab results, make appointments, pay bills, set up automatic alerts and notifications, and manage health information for the entire family. We continue to see rapid adoption, with more than 2,000 new patient registrations each week, and we remain on track to launch the portal nationwide later this year."

Managed Care Trends

LabCorp's executives did not discuss "narrow provider networks" during their conference call. Instead, the emphasis was on how both health insurers and integrated health systems were likely to address utilization of laboratory tests and other clinical services.

"I think that there is increasing focus in managed care on... the trend of utilization," observed King. "And it's also what tests are being selected. ...it's not just managed care by the way, it's integrated delivery networks, it's health systems, [that] are focused on what tests are being ordered, why tests are being ordered, and if they are being ordered from the right provider."

LabCorp is prepared for what it estimates will be a 5% reduction in Medicare Part B lab test reimbursement for 2013. It believes that those laboratories that do well in future years will be efficient and low cost.

"The higher-cost, less-efficient providers are going to be disadvantaged," declared King. "And the more-efficient providers—particularly the high-quality, more-efficient providers like LabCorp—are going to be in a strong position."

Used in subspecialist pathology consultations

Pathologists in China, U.S. Linked By Digital Pathology

CEO Summary: It is one of the first clinical collaborations of this type to be anchored by use of digital pathology. Pathologists at the medical schools of the Second Affiliated Hospital of Zhejiang University in Hangzhou, China, and the University of California Los Angeles (UCLA) are exchanging cases and sharing knowledge. During the first 18 months of this unique relationship, the volume of cases shared via digital pathology has grown steadily.

PART TWO OF A SERIES

EDITOR'S NOTE: Perhaps nowhere in the world is digital pathology more transformational than it is right now in the People's Republic of China. At the forefront of these developments is a unique digital pathology relationship that spans the Pacific Ocean and connects pathologists in the United States with pathologists in China.

Partners in this digital pathology collaboration are the pathology departments of the David Geffen School of Medicine at the University of California Los Angeles (UCLA), and 2nd Affiliated Hospital of Zhejiang University (SAHZU) School of Medicine, in Hangzhou, China.

Part one of our coverage presented the digital pathology relationship from the perspective of the Chinese pathologists. It was based on interviews conducted by THE DARK REPORT during its site visit to the pathology laboratory in Hangzhou, China. *(See TDR, July 16, 2012.)*

Part two, presented here, tells the story as viewed by an American pathologist. It is an interview with Scott Binder, M.D., Senior Vice Chair, Pathology and Laboratory Medicine at UCLA. He is actively involved in the collaboration with the SAHZU pathologists and had just returned from a trip to China.

EDITOR: First, I must tell our readers that all the pathologists engaged in this clinical and teaching collaboration that is anchored by digital pathology—whether in China or in the United States—are quite enthusiastic about the exchange of knowledge.

BINDER: There is a reason for this enthusiasm. Pathologists at these two institutions are using digital pathology to work collaboratively to improve the practice of pathology in dramatic and startling ways.

EDITOR: That has been my impression as well. During my site visit to SAHZU in October 2011, I visited both the clinical laboratory and the anatomic pathology department. This is a 1,500-bed hospital and each laboratory was well-equipped with the latest lab analyzers and automated systems. But I could see that the volume of testing performed at this hospital is noticeably less than what would be typical in the United States. Could you comment on that?

BINDER: These Chinese hospitals have some of the best laboratory equipment in the world. However, keep in mind that China's rapid economic development only started a couple of decades ago. This is a healthcare system that is modernizing at an astounding rate.

EDITOR: What the pathologists in China told me is that economic growth is moving large numbers of people into the middle class. As this happens, these people want the best healthcare their money can buy.

BINDER: That is correct. In turn, it is why the medical schools in China are motivated to train new doctors to deliver state-of-the-art medicine. Professors of pathology and laboratory medicine must themselves acquire these advanced skills across the entire spectrum of laboratory medicine—then teach these skills to their medical students.

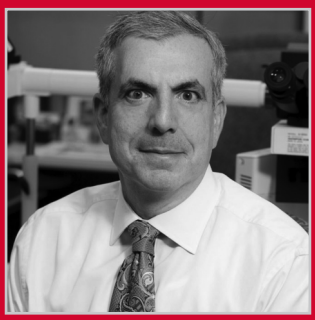
EDITOR: You describe a situation where demand for healthcare services in China currently outstrips the supply of pathologists (and other physicians) who are trained in the latest medical techniques.

BINDER: The numbers tell the story. China is a nation of 1.3 billion people. In part one, you shared the statistic from the Chinese Ministry of Health that there are 14,000 public hospitals, plus 5,700 private hospitals in China. Yet there are only about 20,000 pathologists in this nation—hardly one pathologist per hospital! Moreover, most of these pathologists do not have the depth of training in laboratory medicine that is typi-

cal in the United States and Northwestern Europe.

EDITOR: Your observations make it easier to understand why there is keen interest in China to train more pathologists. It also explains the motivation for medical schools to upgrade the quality and content of their training programs for young doctors. Isn't it true that the relationship between the pathology departments at UCLA and SAHZU came about because of earlier agreements between the parent universities?

BINDER: Yes. Almost one decade ago, the original agreement created a nanotechnology institute involving **Zhejiang University** and UCLA (that included both the university itself and our medical school). From this first initial shared project, a similar exchange developed between the respective medical schools and health systems of the two institutions. It is for these reasons that Zhejiang University is considered our sister university in China.



Scott W. Binder, M.D., is Senior Vice Chair of Pathology and Laboratory Medicine at the University of California, Los Angeles (UCLA). Binder is also Chief of Dermatopathology and serves as the Director and Pathologist of UCLA's Biomarker Innovations Laboratory.

EDITOR: You emphasize the exchange of knowledge as a cornerstone of this unique, ongoing relationship between the pathologists at SAHZU and the pathologists at UCLA. Could you speak to how digital pathology is used to support this exchange of knowledge?

BINDER: Digital pathology forms the basis for the knowledge exchange because it eliminates the need to ship glass slides back and forth across the Pacific Ocean. It allows pathologists at both sites to view the same images in real time during consultations, tumor boards, and similar interactions.

EDITOR: What digital pathology system is used by each pathology laboratory?

BINDER: We both have the system designed by **Aperio Technologies, Inc.**, of San Diego, California.

EDITOR: What is the best way to understand the ongoing relationship between your two pathology laboratories, how they interact, and the ways in which digital pathology is a tool that supports this activity?

BINDER: At the center of this relationship is the role of UCLA pathologists as the source of second opinions and consultations.

EDITOR: Explain that in more detail, please.

BINDER: Pathologists at SAHZU use us for subspecialist second opinions, mostly on tumor cases. This is also consistent with how the **Food & Drug Administration** (FDA) wants the digital pathology system to be used for clinical purposes.

EDITOR: Are these second opinion cases discussed at regular sessions?

BINDER: Yes. At least once every month, a tumor board is conducted with the SAHZU pathologists. With the growth in case volume, there are some months when we have two tumor board meetings.

EDITOR: To date, how many cases have been handled using the digital pathology system?

BINDER: It's been more than 18 months since the digital pathology relationship commenced. Early in this arrangement, it was just a handful of cases, maybe totaling 300 during that first year, or about 25 cases per month. Currently, the volume has grown to about 100 cases per month

and we project that, by the end of this year, there will be a total of 1,500 cases handled via digital pathology.

EDITOR: I am curious about one point. During my interview with Li-Rong Chen, M.D., Ph.D., Director, Professor, Chief Doctor, Department of Pathology, at SAHZU, he mentioned that there is a shortage of pathologists in China. Is the emphasis on referring cases to UCLA for second opinions one way that Dr. Chen and his colleagues can expand their capacity to handle a larger volume of cases?

BINDER: That is one benefit for them in having us provide subspecialty expertise. But much more significant is the knowledge exchange and training that happens when their pathologists interact with our pathologists.

EDITOR: You are emphasizing that the knowledge exchange is primary.

BINDER: That is true. Keep in mind, each case was first diagnosed by a Chinese pathologist. Their interest is only in second opinions.

EDITOR: What are some of the benefits for the UCLA department of pathology?

BINDER: First of all, the cases we get from them are extremely interesting and unusual because the diseases are unusual. That means that there is always a teaching element involved, which is critical to everything we do at UCLA.

EDITOR: Is this digital pathology relationship creating other opportunities for your pathology department to do business in China? We always read about the exploding demand for luxury goods and all types of top quality services—including healthcare.

BINDER: Yes, there are other opportunities. I just returned from a trip to China where I met with a number of companies, hospitals, and private medical laboratories. The UCLA brand is strong in China, for reasons I will explain in a moment.

EDITOR: It sounds like there is active development of other collaborations involving UCLA and organizations in China.

BINDER: That is definitely true. Our pathology department is talking to other companies in China about using telepathology as a gateway to doing additional partnerships and creating new business models. This demand and high interest is driven by the tremendous need for esoteric testing in China. There is also a substantial and untapped demand for reliable second-tier testing and for reliable immunohistochemistry and flow cytometry.

EDITOR: All of this seems to be related to the fast growth of the Chinese economy and the demand for sophisticated healthcare services.

BINDER: As you mentioned, many Chinese hospital laboratories have the most expensive and newest lab analyzers and automated systems. But the lab staff lacks the training to run this equipment. For example, they cannot interpret some of the more sophisticated test results or troubleshoot when test results are not as expected. Chinese labs generally don't have the quality control and quality assurance (QA/QC) of labs in the United States and Europe, for example.

Scott Binder, M.D.

➤"We are talking to other companies in China about using telepathology as a gateway to doing other partnerships and creating other business models."

EDITOR: This is interesting. You are describing that gap between resources and skilled lab scientists that we discussed earlier. There is the money to afford the most sophisticated, latest-generation laboratory analyzers, but there are inadequate numbers of pathologists and clinical laboratory scientists who are trained and able to perform testing at the full potential of these instrument systems.

BINDER: It gets even more interesting. One reason for this situation is that, historically, pathologists have not been held in high esteem. Pathology is a low-pay, low-status profession in that country.

EDITOR: How is that changing, if it is?

BINDER: The status of pathologists, and laboratory medicine in general, is increasing. It is because of the rise of a large middle class and the growth of the upper class. Suddenly, these people realize that they need to get the correct diagnosis. And they find that they cannot get into clinical trials unless they have a correct diagnosis.

EDITOR: That is interesting. You describe a trend where patients are becoming more aware of the importance of having an accurate diagnosis of their medical condition.

BINDER: Most definitely! Once these patients—who have the economic means to pay for quality healthcare—saw these failings, they started to demand that they get a correct diagnosis. That puts pathologists front and center because of their role in performing and interpreting laboratory tests.

EDITOR: Does brand awareness have a role in the growing appreciation that accurate pathology and lab testing is essential to better patient outcomes?

Scott Binder, M.D.

➤"[In China,] the status of pathologists, and laboratory medicine in general, is increasing... because people realize that they need to get the correct diagnosis."

BINDER: Yes, and that brings me back to my comments about the value of the UCLA brand. As you may have seen, Robert, during your trip to China, as a people, the Chinese want quality. For that reason, they are extremely brand-oriented. They want the highest-quality name brands for shoes, purses, clothes, cars, and now medical care.

EDITOR: Thus, your UCLA brand of pathology has high value in China.

BINDER: Yes. In particular, it is why medical schools, hospitals, and private health companies in China want to work with UCLA, **Stanford**, and **Mayo**—the best cancer institutes and diagnostic centers. That translates into a strong interest in raising the level of quality in pathology and lab accuracy and in the precision of diagnosis. Also, there is strong interest in correlating the results of pathology testing with appropriate clinical care.

EDITOR: You are pointing out that improved diagnostic accuracy is a major goal for this digital pathology collaboration between UCLA and SAHZU.

BINDER: In dealing with patient cases, that is definitely true. Our subspecialist pathologists provide seamless and relatively rapid, second opinion consults. Our diagnoses can sometimes vary greatly from what the SAHZU pathologists were thinking and how they were working up these cases. This is where a rich learning exchange takes place and that is the ideal for both pathology departments. Their pathologists come here to study. Our pathologists go there to learn what they are doing and to better understand the context of how patients are diagnosed and treated.

EDITOR: One point that will interest pathologists in the United States is how pathologists in China are paid. During my site visit to Second Affiliated Hospital of Zhejiang University (SAHZU) in Hangzhou, I was told that the payment rate is about 100 Chinese yuan per outpatient diagnosis. That would work out to about US$15 per case.

BINDER: $15 per case would be correct.

EDITOR: Was it your impression that in China there was a very clear division between anatomic pathology and what we would call clinical laboratory?

BINDER: Yes, that's true. And, also, the blood bank is completely separate as well, as it is in Europe.

EDITOR: Can you describe the direct benefits to UCLA over the 18 months of the relationship? What has been positive for you, your department, and your colleagues?

BINDER: First, the most important positives have been the collegial exchange of these cases and the education of the residents regarding these unusual cases. Second, this digital pathology relationship is opening up channels that allow us to discuss larger pathology ventures with other players in China.

Scott Binder, M.D.

➤"...the most important positives have been the collegial exchange of these cases and the education of the residents regarding these unusual cases."

EDITOR: Is there much revenue associated with these cases and relationships?

BINDER: Revenue is a third benefit. This year, we expect to get close to 1,500 specimen consults. That won't generate a lot of money, but it adds up. More importantly, as UCLA develops its pathology network in China over time, there could be a sizeable amount of income in the future.

EDITOR: Could you discuss the clinical aspects of the digital pathology collaboration in more detail? What are some of the unique types of cases that you see?

BINDER: The keys to this relationship are the educational and research opportunities. The tumor boards give us an opportunity to exchange clinical information with them, and when we do, we find their clinicians are very much up to date.

EDITOR: Scott, as a board-certified dermatopathologist, what do you see happening in that field?

BINDER: I recently spent a day with dermatologists in China. I gained a lot of respect for their clinical acumen, which is similar to that of the clinicians here at UCLA. They are much less interested in cosmetics and lasers and much more interested in medical dermatology. I find the clinical-pathological correlation to be very exciting—in part because they are excellent clinicians and because they have phenomenal cases.

EDITOR: I would assume that, in a country as large as China, that they see a variety of cancers and infectious diseases that reflect their environment and are different from the types of cases seen here.

BINDER: That is a good observation. The cancers are related to their diet and the environment and tend to affect the liver, GI tract, and lungs. They also have breast, ovarian, bone, and brain tumors.

EDITOR: What do you see in the way of infectious disease cases?

BINDER: Interestingly, tuberculosis is still a major disease there. They often see people from rural areas who have deep fungal infections. Leprosy is another infectious disease that we have seen.

EDITOR: Are there types of cancers where the UCLA connection has helped the SAHZU pathologists expand their clinical services?

BINDER: That would involve cases of lymphoma and leukemia, which they have not worked up in the past. The leukemia patients basically are characterized as AML, ALL, and CML. But few laboratories in China are equipped to handle cytogenetic testing, flow cytometry, and the additional studies needed to help guide treatments and prognoses. That makes it very exciting for us to work with them in hematopathology.

EDITOR: Are there other areas where you've been able to help them improve the range of pathology services they offer to their referring physicians?

BINDER: The best way to answer that question is that this digital pathology collaboration is really about them. For us, the bottom line is improving the delivery of healthcare, seeing these interesting cases, and teaching the residents.

EDITOR: You are emphasizing that pathologists in both countries are learning a great deal from this relationship.

BINDER: That is true. We bring them world-class expertise in pathology. That is important because so much medicine in China is still that of the second world. Conversely, because of a long-time emphasis on surgery, China has excellent clinicians who are doing lots of transplants and technical surgery.

EDITOR: That reflects uneven development in their healthcare system.

BINDER: In pathology and lab medicine, it might be said that the training and general service levels are stuck in the 1980s. Now, as they acquire 21st century lab analyzers and automation, they need to put these technologies to their best use.

EDITOR: In working to help the SAHZU pathologists advance their skills and acquire more sophisticated knowledge, is there any common learning curve they experience?

Scott Binder, M.D.

➤"We are consistently impressed with the level of intelligence and commitment of our Chinese colleagues. They care deeply about delivering quality results."

BINDER: That is an interesting question. There is a certain step-by-step learning process. Some of their pathologists have spent time in our lab. As well, some of our pathologists have gone there. These are smart pathologists and eager to learn.

EDITOR: Does the learning start with how to order the right tests?

BINDER: That is correct, since, initially, they didn't know which tests to order for certain cases. We helped them with that. We are teaching them the importance of good technique. It is essential that they know how to interpret results, particularly for the sophisticated cases. One reason is because their practice of pathology is still primarily at the H&E (hematoxylin and eosin stain) level.

EDITOR: This probably goes back to the original training that was given to these pathologists.

BINDER: You make a good point and I would like to comment on that. We are consistently impressed with the level of intelligence and commitment of our Chinese colleagues. They care deeply about delivering quality results. They became pathologists because they are interested in the science of pathology and laboratory medicine. It just so happens that, in China, pathology is a low prestige field. The resources were not there during their training.

EDITOR: Traditional Chinese medicine is rooted in a much different philosophy than Western medicine. Would you comment on how that influences the development of "modern medicine" in China, along with the way pathologists are trained in that country?

BINDER: The answer lies in the Chinese culture. The foundation of their traditional medicine had no pathology as we recognize in Western medicine.

EDITOR: Please continue.

BINDER: Traditional medicine in China is centered upon physiology and anatomy. The emphasis is on assessing the yin and the yang, or the humours. The practitioner looks at the body to ensure that it is in balance. But this method of practice is not about pathology as it is defined in Western medical practice. Traditional Chinese medicine never viewed pathology as a central issue. Nor was it made part of their medicine.

EDITOR: Conversely, of course, pathology is the foundation of western medicine.

BINDER: Agreed. And the growth of genomics and molecular technology makes pathology even more important in Western medicine. For us, medicine is about the tissue. For traditional Chinese practitioners, medicine was about the balance of energy.

Chinese Traditional Medicine Was Slow to React To 19th Century Medical Advances in Europe, U.S.

THERE IS AN INTERESTING REASON why pathologists in China traditionally did not get the respect they are now gaining as today's Chinese patients recognize the importance of an accurate diagnosis.

It is the fact that traditional Chinese medicine—anchored in the philosophy of the balance of energy that would be revealed by assessing the yin and the yang—never incorporated the exciting medical advances of the 19th century into their medical thinking.

During that era, physicians and scientists in the nations of Germany, England, and France developed the foundations of modern medicine. One important figure was Rudolph Virchow who lived in Berlin, Germany. He is the pathologist generally recognized as the father of modern pathology.

Virchow, who lived from 1821 until 1902, described many pathological processes in detail. He also developed appropriate terminology and a classification system.

Virchow's cellular pathology "destroyed the old humoral pathology and created the doctrine of cell physiology and pathology" that opened a new epoch in medical science, according to an article published last year in the Russian publication, *Arkhiv Patologii*.

For pathologists in China, rapid economic development has brought new opportunities to deliver more value to referring physicians and their patients. In turn, the need to acquire more sophisticated diagnostic skills is the motivation behind several of the international collaborations that have been announced between labs in the U.S. and China.

EDITOR: I suspect most readers overlook the role traditional Chinese medicine has had in shaping the thinking of both patients and physicians in that country. Those insights reinforce why the relationship between the pathology departments of UCLA and SAHZU is highly valued by both parties.

BINDER: One cannot ignore the influence of traditional Chinese medicine. On the other hand, it bears repeating that the Chinese people are driving the current revolution in healthcare in their country. That is because they are willing to pay for the best care in pathology.

EDITOR: You are emphasizing that patients are driving this revolution.

BINDER: Of course. Informed patients—with the money to pay for top healthcare—saw that the diagnoses they were getting were not necessarily the best. And, today, it is the patients in China who are willing to pay so that subspecialist pathologists at prominent institutions like UCLA, Stanford, or Mayo will take a second look and provide a consultation. That is the foundation of the economic model that drives this venture.

EDITOR: At the same time, this economic model of the patient who is willing to pay for a second pathology opinion is what creates the foundation for the exchange of clinical knowledge and medical training between the pathology departments at SAHZU and UCLA. It is interesting how economics is always intertwined with clinical practice.

BINDER: That is true. Today, we are simply opening the door to that sleeping giant called China. There is every reason to expect that, as their healthcare system develops, their pathologists will eventually be recognized as world-class. It may take some time for them to catch up to the West, but they have a strong start.

EDITOR: Thank you, Scott, for your insights into the value of digital pathology and UCLA's collaboration with pathologists in Hangzhou, China. **TDR**

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Lab Briefs

LEICA BIOSYSTEMS TO ACQUIRE APERIO

FOR THE SECOND TIME IN AS MANY YEARS, a global leader in histology systems and products has announced that it will acquire one of the leading digital pathology companies. This time it is **Leica Biosystems** of Nussloch, Germany, which will purchase **Aperio Technologies, Inc.**, of Vista, California.

Founded by Dirk Soenksen in 1999 in his garage, Aperio grew steadily and has stated that it has more digital pathology systems in use around the world than any other digital pathology company. In recent years, the company has acknowledged an installed base of more than 700 systems in 30 countries.

Leica's strategy is to develop an integrated suite of pathology products and systems that include histology and the pathologist review of the case. There is the opportunity to develop proprietary assays that incorporate both specimen processing and diagnosis of the resulting images.

APPEALS COURT DECISION IN MYRIAD CASE

IT'S BEEN AN EVENTFUL YEAR for legal cases challenging gene patents. In the case of *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the latest development came on August 16, 2012.

That is the day when the U.S. Court of Appeals for the Federal Circuit (CAFC) confirmed an earlier ruling that DNA molecules isolated from their natural state are patentable subject matter. The Supreme Court had earlier directed the appeals court to review its previous decision in this high-profile legal case.

In commenting on the matter, the law firm **Bradley Arant Boult Cummings, LLP**, in Birmingham, Alabama, said, the ruling means "that certain method claims directed to identifying anti-cancer compounds were patentable, but certain diagnostic method claims directed to methods of analyzing and comparing the sequences of DNA molecules were not patentable."

This ruling is significant because, "While this decision protects inventors' rights in isolated DNA molecules and some methods of using isolated DNA, this decision casts some uncertainty in the area of patentability for diagnostic genetic testing," it added.

Last year, the federal appeals court had ruled that isolated DNA was patentable and that certain method claims were if directed to patentable subject matter, while certain method claims were not. The U.S. Supreme Court vacated this decision, however. It then ordered CAFC to reconsider the case in light of the Supreme Court's ruling in the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the law firm said.

HOLOGIC COMPLETES GEN-PROBE ACQUISITION

SEEKING TO BE THE MARKET LEADERS in testing for the human papillomavirus (HPV), **Hologic, Inc.**, of Bedford, Massachusetts, completed its acquisition of **Gen-Probe Inc.**, of San Diego, California.

Hologic paid $3.8 billion. Gen-Probe holds significant market share of testing for chlamydia, gonorrhea HIV, hepatitis B and hepatitis C. It is developing a test for HPV. Hologic already has an HPV test that it acquired when it paid $580 million to purchase **Third Wave Technologies**, of Madison, Wisconsin, in 2008.

HPV is the leading cause of cervical cancer worldwide and the market for cervical cancer screening is one of the biggest. In the United States alone, some 55 million cervical cancer screening tests are performed each year. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

How big is the market for laboratory testing in China, with its 20,000 hospitals and population of 1.3 billion people? A new report estimates that the independent clinical laboratory industry in China currently generates about 2 billion Yuan Renminbi per year in revenue. This is equal to about US $315 million. Authors of the report, issued by **Companies and Markets** of London, England, state that independent clinical laboratories make up just 1% to 2% of the total market for medical diagnosis. By comparison, in the United States, it is estimated that clinical laboratory testing from all sources represents about $60 billion per year in revenue.

MORE ON: *Chinese Clinical Laboratories*

The report authors estimate that there are currently 110 independent clinical laboratories in China. Identified as the largest lab companies are: **Kingmed Diagnostics**, **Zhejiang D.A. Diagnostics**, **ADICON Clinical Laboratories, Inc.**, and **Gaoxin-Da An**. American companies are investing in these Chinese labs. For example, the report states that "In March 2012, **Kindstar Global (Beijing) Medical Technology** secured US $20 million in Series C funding from such investors as **KPCB China**, **WI Harper Group**, **Baird Capital Partners Asia**, and **Mayo Clinic**, of which the latter three companies also participated in the company's Series B financing of USD $11 million in June 2011."

27 MONTHS IN JAIL FOR EX-LABCORP MANAGER

It is the latest example of "true crime" in the lab industry. News media in St. Louis, Missouri, are reporting that Eric Engle, former manager of the North Central Division of **Laboratory Corporation of America**, was sentenced to 27 months in jail following his guilty plea to one felony count of wire fraud last March. Engle worked at LabCorp from 2004 until September 2011. In the charges brought against him by the U.S. Attorney of Eastern Missouri, it was claimed that Engle created OptiClean, a ficticious cleaning service company. "He allegedly created false invoices from OptiClean and then, in his capacity as a LabCorp supervisor, faxed them to LabCorp in North Carolina. LabCorp would then pay the bills and mail checks to a St. Louis post office box, according to the charges." Engle's scam generated $342,430 in payments for services never rendered, according to news reports.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 17, 2012.

It's New!

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Steve Stone, of Argent Global Services on:

How to Conduct Your Assessment of Products And Systems Before Purchase

There's good news for you when it's time to replace existing equipment or purchase new analyzers and automated systems! You can use the same techniques of Lean, Six Sigma, and process improvement to evaluate different products before you buy. Learn how to recognize the strengths and weaknesses of competing products. Master the proven secrets of matching the right product to your lab's specific needs. Join us for this powerful session!

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- ***Assessing the Clinical and Financial Impact of Changes to Medicare Prostate Biopsy Rules.***
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