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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

Lab Testing Hits Two Home Runs For Patients

MANY OF US POINT OUT THAT LABORATORY MEDICINE is an undervalued and under-utilized asset within the American healthcare system. Lab testing is generally a minimal cost relative to the total episode of care, yet lab testing provides essential knowledge to help clinicians make a quick, accurate diagnosis and confidently select appropriate therapies.

Like the late comedian Rodney Dangerfield, many lab directors and pathologists feel like "I don't get no respect!", particularly when negotiating contracts with managed care plans. Seldom is the true value of laboratory testing acknowledged by payers, particularly in the form of adequate reimbursement.

However, this situation may be on the verge of changing. In this issue of THE DARK REPORT, we provide intelligence briefings on two important home runs hit by laboratories during the past 24 months. First up is our coverage about the explosion in vitamin D testing. Labs across the country are reporting that vitamin D test volumes have doubled and tripled over the most recent 12 months! **ARUP Laboratories** tells us that about one-third of the vitamin D test results indicate that the individual is vitamin D-deficient. This fact is evidence that physicians are using the test appropriately. *(See pages 3-5.)*

That remarkable lab testing home run is followed by the story of another, even more amazing lab testing home run. At **Washington Hospital Center** (WHC) in Washington, DC, a rapid PNA FISH test for bloodstream infections, combined with real-time results reporting to the attending physician, has contributed to an 83% drop in patient mortality in ICU settings—and a 53% overall reduction in patient mortality related to bloodstream infections! *(See pages 6-9.)*

The unique twist to the WHC experience is that these dramatic reductions in patient mortality only came after the procedure for reporting the PNA FISH tests was changed to incorporate a personal phone call to the attending physician, to ensure he/she got the results in real time.

Now comes the next challenge for the lab industry. Will Medicare and private payers recognize this value provided by labs to their referring clinicians? Will Medicare and private payers establish reasonable reimbursement for these testing services? Too often in the past, payers publicly promote the importance of patients getting these tests, while, in private, they excoriate labs for not controlling test utilization and financially penalize them for the higher volume of testing that was performed. TDR

Vitamin D Test Volumes Doubled in Past Year

Growing awareness about vitamin D deficiency causes patients and physicians to order more tests

CEO SUMMARY: Across the nation, labs report a near doubling in the volume of vitamin D tests they are performing. This is a success for laboratory medicine and an appropriate use of diagnostics tests as physicians strive for early detection and early intervention of vitamin D deficiency. However, the next chapter in this story will be equally important. Will Medicare and private payers recognize that, per evidence-based medicine guidelines, this testing is justified and labs should not be punished for increased utilization?

CLINICAL LABS ACROSS THE COUNTRY are doing about twice as many tests for vitamin D deficiency this year as they did last year. This increase is due to the concerns of both patients and physicians that aging Americans are not getting sufficient levels of vitamin D, thus causing a deficiency that can lead to ill effects, such as bone loss, cancer, and diabetes.

To find out more about the increased utilization of vitamin D testing, THE DARK REPORT contacted A. Wayne Meikle, M.D., Medical Director of the Endocrinology and Automated Endocrinology Laboratory at **ARUP Laboratories,** a national reference lab in Salt Lake City, Utah. Meikle also is a Professor of Medicine, Endocrinology, and Pathology at the **University of Utah School of Medicine**.

"For the past year, ARUP's database shows that our laboratory has seen an increase of more than 100% in the number of tests we performed for vitamin D deficiency," reported Meikle. "Last year, we averaged about 40,500 vitamin D deficiency tests per month. This year, that has increased to an average of about 82,000 tests per month.

"I believe the increase is a result of a combination of physicians recommending the test to their patients and patients asking their physicians for this test," added Meikle. "There has been extensive press about the health issues related to vitamin D deficiency, and much of the media coverage has included education on the value of maintaining vitamin D levels. At the same time, physician awareness has increased as they realize how common vitamin D deficiency is among their patients."

Earlier this month, *USA Today* published an article about heightened awareness of vitamin D deficiency. It included lab

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testing data. It noted that **Quest Diagnostics Incorporated** of Madison, New Jersey, reported that tests for vitamin D grew by about 80% from May 2007 to May 2008. **Laboratory Corporation of America,** in Burlington, North Carolina, acknowledged a 90% increase in tests for vitamin D levels from 2007 to 2008. Neither company would release the actual numbers.

USA Today also reported that the **Mayo Clinic**, in Rochester, Minnesota, processed 424,582 tests for vitamin D deficiency last year, which represented an increase of 74% over the number of such tests it ran in 2006. Mayo expects to run more than 500,000 such tests this year.

➤Test Volume Has Tripled

It's a similar story at **Kaiser Permanente**. "The volume of vitamin D tests has skyrocketed!" declared Thomas S. Lorey, M.D., Director of the Regional Laboratory for Kaiser Permanente Northern California, which provides testing for approximately three million beneficiaries. "Our volumes have tripled in the last year, and we don't feel that we have yet reached a plateau."

This stunning and rapid increase in the utilization of Vitamin D testing by patients and physicians—unrecognized by the broader laboratory industry until this DARK REPORT intelligence briefing—is likely to be a landmark development. It demonstrates new implications from fast-moving reforms to the American healthcare system.

First, this shows how quickly newly-issued evidence-based medicine (EBM) guidelines can change clinical practices—and dramatically alter long-standing laboratory medicine experience and test-ordering patterns. With little warning, the laboratories referenced above have seen a near-doubling of vitamin D tests in just 12 months!

Second, Meikle specifically mentioned the public's rapid acceptance of the need for vitamin D deficiency testing. It shows that informed consumers are taking an active role in their care and requesting that their physicians order these tests.

That raises an interesting question. Since, historically, clinicians in this country have been famously slow to incorporate new clinical knowledge into their daily practice, is this doubling of vitamin D testing in less than a year a demonstration of new-found consumer power in healthcare? If this is true, it is a powerful signal to laboratory administrators and pathologists. Over time, their laboratory organizations may be in peril if they fail to address the changing role of the consumer in healthcare.

Third, the payer response to this development has yet to be seen. There is every reason to believe this testing is being performed in appropriate situations. Thus, laboratories should not be financially-penalized because utilization of vitamin D testing has doubled and the payer's lab spend has increased proportionally.

The laboratory industry, and its lobbying groups, should not allow the payer community to double-deal as it has in the past. Often, payers, including Medicare, publicly claim support for evidence-based guidelines, and, as in the case of increased vitamin D testing, affirm it is the right and proper way to achieve early diagnosis and early intervention because it improves downstream patient outcomes and lowers the long-term cost of care.

➤Payers Try To Cut Lab Costs

Yet, these same payers, quietly out of the public eye, when it comes time to negotiate fees with laboratories, complain that test utilization has gone up and the laboratory's job is to control that utilization. As a consequence, payers often force laboratories to accept less reimbursement because of the increased test utilization.

For these reasons, this episode of increased vitamin D testing will teach lab administrators and pathologists some useful lessons about how to respond, in the future, when a new evidence-based medi-

Labs Have Opportunity to Help Physicians By Providing Vitamin D Testing Pathways

VITAMIN D TESTING IS AN OPPORTUNITY for local laboratories. "To support physicians, use of diagnostics pathways would help clinical labs explain the issues involved in vitamin D testing," explained A. Wayne Meikle, M.D., Medical Director of the Endocrinology and Automated Endocrinology Laboratory at ARUP Laboratories. "Here at ARUP, we do two tests. One is called vitamin D 25 and one is called vitamin D, 1, 25. We have seen an increase in both tests, but mostly the increase has come in volume for the vitamin D 25 test, as it should be.

"Because some physicians may be unaware of which test they should order, they will order both," Meikle said. "Often when an order comes in for vitamin D 1, 25 to diagnose vitamin D deficiency, usually what the physicians should order is the vitamin D 25 test instead. That's why use of pathways would be appropriate.

Choosing The Right Test

"With vitamin D deficiency, the patient's parathyroid hormone level goes up, which can leach calcium out of bone and contribute to the development of osteoporosis," Meikle explained. "When the parathyroid hormone level goes up, the vitamin D 1, 25 level may be quite normal. That's why the vitamin D 25 test should be used when testing for a deficiency.

"Another problem with diagnosing vitamin D deficiency is our routine chemistry tests don't give us a clue that an individual may be deficient," he added. "The calcium level may be perfectly normal, leading the referring physician to think everything is fine. That's why a referring physician needs to be specific in measuring vitamin D 25 to confirm the deficiency.

"In fact, I analyzed our database to see how many individuals among all of our patients are deficient," said Meikle. "About 30% of the individuals we have tested have a vitamin D deficiency. That's quite a high percentage.

"A number of factors can contribute to low levels of vitamin D and many people are not aware of these factors," he continued. "As an endocrinologist, I see these people clinically and it's clear that one factor that contributes to vitamin D deficiency is that, as people age, their skin is less efficient at making vitamin D from sunlight or ultraviolet light. Another factor is people, as they age, tend to drink less milk and so their intake of calcium is reduced. For these two reasons, older Americans are set up for a vitamin D deficiency, and, as we know, we have an aging population.

"Another reason that many patients may not make enough vitamin D is their concern about being overexposed to sunlight. Use of sunscreen effectively blocks the benefit we get from the sun," Meikle said. "So, we have a choice: Do we want to risk skin cancer or use sunscreen and have a vitamin D deficiency?

"In addition to these concerns, many patients do not normally get enough vitamin D in the diet or with supplements," Meikle said. "For all of these reasons, it is certainly appropriate for referring physicians to screen patients who are over age 50 for a vitamin D deficiency.

"The recommendations for how much vitamin D an individual should get has steadily gone up among physicians who have studied vitamin D and its metabolite consequences," he added. "A few years ago, for a person over age 60, these physicians recommended supplementing the diet with 600 units of vitamin D each day. Now, they want the total intake to be 1,200 units for a person over 60 years or older."

cine guideline triggers a substantial increase in laboratory testing in support of the EBM. At a minimum, this sudden rush of vitamin D testing tells us that changes are definitely afoot in the U.S. healthcare system. **TDR**

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53% Drop in Mortality From Lab Report Change

➤Study links use of rapid molecular test and real-time results reporting to improved outcomes

➤➤CEO SUMMARY: At Washington Hospital Center, it was unclear if the use of a rapid molecular assay for blood infections was changing outcomes until a new, real-time lab results reporting protocol required the lab to deliver the test results personally to the attending physician in real time. A study with a control group provided convincing evidence that use of the rapid molecular test, in combination with real time test reporting, may be associated with dramatic reduction in mortality and improved patient outcomes.

FOLLOWING INTRODUCTION OF A MOLECULAR ASSAY and a simple change in laboratory test reporting procedures, **Washington Hospital Center (WHC)** in Washington, DC, saw a 53% reduction in deaths associated with *Staphylococcus aureus* bloodstream infections. This achievement demonstrates how a proactive laboratory team can contribute to better outcomes and other benefits.

Recognizing the challenges labs have in delivering real-time test results to busy physicians, the laboratory at Washington Hospital Center, a 926-bed tertiary care facility, developed an unusual way to report results: it called physicians directly to report its PNA FISH test findings. The result was reduced mortality and costs, as well as and more efficient use of antibiotics, said Shmuel Shoham, M.D., Director of Transplant Infectious Diseases at WHC.

Shoham was one of several authors of a study published recently in *Therapeutics and Clinical Risk Management*. Titled "Impact upon Clinical Outcomes of Translation of PNA FISH-Generated Laboratory Data from the Clinical Microbiology Bench to Bedside in Real Time," Shoham and colleagues reported that the direct reporting protocol helped: 1) to cut mortality among 101 patients by about half; 2) to decrease median charges from $92,373 to $72,932; and, 3) to reduce use of antibiotics from three days to one day.

The study's findings are significant because each year, some 350,000 patients in the United States have bloodstream infections, causing more than 90,000 unnecessary deaths and significant costs to the healthcare system. The infection is detected when a blood culture turns positive with bacteria and yeast. Rapid and accurate identification of the specific pathogen is needed to ensure early and appropriate therapy.

➤Improving Outcomes

"We did this study because it is my belief that information that is not transmitted is information that is potentially lost," Shoham said. "We needed a way to transmit this information in a timely manner."

Washington Hospital Center had used the peptide nucleic acid-florescence *in situ* hybridization (PNA FISH) test since 2003

Use of Rapid Molecular Test, Real-Time Reporting Contributes to Fewer Deaths, Better Outcomes

BLOODSTREAM INFECTIONS resulting from *Staphylococcus* bacteria are a concern for healthcare providers and hospital administrators because they are a leading cause of hospital-acquired infection and mortality.

These infections are initially diagnosed when a culture of a patient's blood turns positive with gram-positive cocci in clusters (GPCC), indicative of staphylococci. Because conventional laboratory identification methods can take 48 hours or longer, it means treating clinicians can't determine whether: a) the blood culture was positive due to true infection, requiring aggressive antibiotic therapy, b) whether the gram-positive indication was due to blood culture contamination with coagulase-negative staphylococci (CoNS), a group of common skin bacteria, so that no antibiotic therapy is required.

This contributes to situations where patients with true infections are undertreated and where patients with contaminated blood cultures (false positives) are often unnecessarily treated with antibiotics.

Seeing the need for increased caution regarding bloodstream infections, Washington Hospital Center conducted a study with 202 patients. The patients with positive blood cultures containing GPCC were enrolled and blindly randomized into a "notification" group or a "usual care" group. For the 101 patients in the notification group (NG), PNA-FISH results and information on the identified bacteria were reported directly to the treating clinicians, whereas for the 101 patients in the usual care group (UCG), data were entered into the hospital's laboratory information system as usual. Here are the results:

- 61 patients with Staphylococcus aureus; 32 in NG vs. 29 in UCG
- 141 patients with CoNS; 69 in NG vs. 72 in UCG
- 53% drop in overall mortality; 8 deaths in NG vs. 17 deaths in UCG
- 80% drop in mortality rate for intensive care unit patients; 10% (2 deaths) for NG vs. 48% (11 deaths) for UCG
- 82% reduction in mortality rate for ICU patients with Staphylococcus aureus; 10% for NG vs. 56% for UCG
- 67% drop in median antibiotic use after notification of results; median of 1 day for NG vs. 3 days for UCG
- 100% cut in median antibiotic use for CoNS patients after notification of; 0 days for NG vs. 2.5 days for UCG
- A reduction of $19,441 in median hospital charges: $72,932 median charges for NG vs. $92,373 for UCG.

The published study is: "Impact upon Clinical Outcomes of Translation of PNA FiSH-Generated Laboratory Data from the Clinical Microbiology Bench to Bedside in Real Time." *Therapeutics and Clinical Risk Management, 2008:4(3) 637-640.*

and introduced the lab reporting protocol in 2006, Shoham explained. The test and the equipment for it were developed by **AdvanDx** in Woburn, Massachusetts.

"It is exciting to see the results from the Washington Hospital Center study," said Thais T. Johansen, President and CEO of AdvanDx. "It documents how rapid reporting of PNA FISH results can contribute to significant reductions in unnecessary antibiotic use while improving patient care. Of equal importance, however, is how WHC used real-time reporting of this test to save lives.

"If we extrapolate the data to the rest of the United States, PNA FISH has the potential of saving close to 23,000 patient lives, reducing 514,000 days of antibiotic use, and saving $5 billion in hospital charges," Johansen added. "In essence, implementing both PNA FISH and real-time reporting of results to clinicians

could be much more beneficial than the introduction of a new generation of antibiotics to treat patients with bloodstream infections."

Speedier Lab Test Reporting

Shoham observed that more research may be needed before clinicians can extrapolate results from Washington Hospital Center to all hospitals in the United States. But he was clear on one lesson learned at WHC. "In terms of costs and mortality, whenever you have a lab test that allows for rapid diagnostic test results, it would be ideal to couple that test with a way to pass the information to the clinician quickly and efficiently," advised Shoham. "It is clearly a waste of resources to have a rapid diagnostic test when the result then stays in the laboratory computer or is not accessed by the physician.

"We knew that a physician is likely to want the PNA FISH test results right away," he continued. "The test is run twice a day, and after the lab gets the results, we wanted a way to immediately relay that information to our physicians. So we assigned one of our fellows to be a laboratory clinical liaison. Her job was to call the physician who ordered the PNA FISH test and not just leave a message. Her job was to get the physician on the phone and then she read from a prepared script.

"Depending on the results, she would say one of two things," Shoham said. "She would say, 'Your patient has coagulase-negative staphylococci (CoNS) infection in the blood and that is usually associated with a contaminant. It's your patient and you are the clinician and so you make the call.' Or, she would say, 'Your patient has *Staphylococcus aureus* in the blood, which is rarely a contaminant and is a serious infection. And, you're the clinician, you make the call.'

"During an analysis of the protocol, we called the clinician on every other run of the PNA FISH test," Shoham explained. "One group was the control group that got the usual and customary care in our hospital. The other group was given this additional intervention in which we called the clinician. We wanted to see what difference it would make in the outcomes.

"The main difference was that the group that had coagulase negative staph infections had fewer days on antibiotics than was true for patients prior to this new protocol," noted Shoham. "The physicians were getting a call from an infectious disease fellow who was well respected, and the clinicians tended to listen to what she had to say.

"The results showed reductions in mortality, lower costs, and less use of antibiotics," he continued. "What that tells us is that it is clinically effective and cost effective to put someone in place in the laboratory to contact the physicians on the floors and deliver those lab test results, in real time, to the physicians on the floors. The cost of having that person in place is well worth it because you get a treatment decision faster, particularly when dealing with something as dynamic as a bloodstream infection. On one hand, it can be life-threatening and immediate action is essential. On the other hand, if the patient is a false positive, you could stop the antibiotic, not use the central line, and maybe send the patient home.

Reports Called To Doctors

"For the lives saved at WHC, the investment was miniscule," added Shoham. "It required our fellow to spend between one and two hours daily making these calls. Even at $75 an hour, you would be spending $150 a day for someone to make these calls. That's well worth the investment.

"In our study, notification of PNA FISH results by phone seemed to be the main factor in decreasing mortality," Shoham explained. "Those patients were put on antibiotics sooner because we reported the results directly to those physicians—who would then aggressively treat the infection.

"The question now is this: Can we extrapolate from this one study to say that using this notification technique will significantly reduce mortality across the whole United States?" Shoham asked. "I'm not sure. Obviously, getting accurate information into the hands of clinicians faster allows them to make better decisions and that improves outcomes. But before we can make a definitive statement about the value of this reporting technique, I'd like to see this study replicated over a period of time.

Fewer Days, Less Costs

"And, I have another question: Could we automate the delivery of this information so the lab's computer sends the results to the physicians' beeper, meaning that, as long as the doctor is wearing a beeper, he or she would get the result via text message?" he asked. "Or, perhaps we could program the lab information system so that, once the result is available, the computer could automatically page the clinician who wrote the order. The whole principle behind having a rapid diagnostic test is to produce *and* deliver the results quickly and efficiently to the person who has prescribing ability."

Shifting Clinical Paradigm

It is uncommon to find a laboratory test that can play a direct role in reducing patient deaths by as much as 83%, as was achieved at Washington Hospital Center. However, the events at WHC hold a more important lesson for lab directors and pathologists.

Simply said, it wasn't a rapid molecular lab test that made a difference; it was a combination of that lab test and a different level of laboratory service that unlocked the dramatic, even stunning, improvements in detection and treatment of bloodstream infections.

Remember, the PNA FISH test was launched in 2003 and delivered modest clinical benefits. But it was not until 2006, when WHC's lab instituted real-time reporting of PNA FISH results to attending physicians, that patient deaths began to decline by amazing amounts: 82% reduction in mortality rate for ICU patients with *Staphylococcus aureus*; 80% drop in mortality rate for intensive care unit patients; and, 53% drop in overall mortality (per the study in *Therapeutics and Clinical Risk Management*).

WHC's achievements should inspire visionary laboratorians. Laboratory testing and lab consultative services have the greatest clinical leverage and added value when laboratory medicine specialists move beyond their walls to become collaborative, consultative partners with clinicians. TDR

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Molecular Assay Delivers Results in about 3.5 Hours

DNA FISH IS AN EXAMPLE OF HOW ADVANCES IN MOLECULAR TECHNOLOGIES are providing labs with new capabilities to diagnose disease. It is a highly-sensitive and specific fluorescence *in situ* hybridization (FISH) assay that uses PNA (peptide nucleic acid) probes to target species-specific ribosomal RNA (rRNA) in live bacteria and yeast.

PNA FISH was developed by AdvanDX, which is based in Woburn, Massachusetts. (www.advandx.com). According to AdvanDX, "the properties of the non-charged, peptide backbone of PNA probes enable the use of FISH assays in complex sample matrixes, such as blood and blood cultures, which facilitates the development of simple, yet accurate, tests that don't require th extensive sample preparation necessary for other nucleic acid technologies." Microbiology labs can use PNA FISH tests "to provide rapid and accurate identification of bloodstream pathogens directly from positive blood cultures in hours instead of days." The test takes about 3.5 hours to run versus 48 hours for more traditional methods and is performed on an instrument that costs about $5,000.

NEWSMAKER INTERVIEW

Labs Should Build Payer Relationships To Improve Commodity Pricing

"Health plans are interested in improving outcomes and saving money on complex, expensive cases because that's where the money is. At the same time, that's an opportunity for labs to help health plans cut costs while also improving quality. "

—Kerry Kaplan, *President, Healthcare Solutions*

CEO Summary: At the most recent* Executive War College*, Kerry Kaplan, President of Healthcare Connections in Natick, Massachusetts, discussed the results of his national survey of health plan executives on their attitudes toward clinical laboratories. It will be no surprise that these managed care executives consider lab testing services to be a commodity. What will be a surprise are Kaplan's recommendations on how laboratories and pathology groups should develop partnerships with selected payers, rooted in added value services that generate ample reimbursement. In this first of a two-part series, Kaplan also delivers a dose of reality to laboratories as he advises them on how to prepare for the marketplace changes coming in the next five years.

PART ONE OF TWO PARTS

EDITOR: Before this year's *Executive War College*, conducted last May in Miami, you interviewed nine executives from a diverse group of health plans nationwide specifically to learn how they viewed laboratory services and what labs should know about their changing needs. What did you learn?

KAPLAN: Lab directors and pathologists won't be surprised to learn that, for the most part, health plans are generally disappointed with what they get from the clinical laboratories with which they work.

EDITOR: One response to that statement is that laboratories are equally disappointed with the managed care industry. But setting that aside, your objective in conducting this survey was to identify how laboratories could better meet the needs of health plans and be an added-value provider in the future—and thus earn higher reimbursement for these services. What was the most important insight you gained from these survey interviews?

KAPLAN: One common theme is that many managed care executives view laboratory services as a commodity. Another finding is that few laboratories have invested the time and resources needed to develop a more productive relationship with key payers in their communities. Until labs have such relationships, lab testing services will be treated like a commodity by health plans.

EDITOR: Our American healthcare system is undergoing transformation. For example, THE DARK REPORT has covered the predictions of experts, including **McKinsey & Company**, that physician groups, hospitals, and health insurance companies must create new integrated care models and compete for patients in ways unseen for several decades. I'd like to start with this topic, and how this transformation will create positive opportunities for laboratories in their dealings with health plans.

KAPLAN: The problem is that most health care providers—including laboratories—are not preparing for the major reshaping of the American healthcare system that has commenced. I frequently describe the American healthcare system as being perfectly poised for the 20th century. We are stuck with a healthcare system that regularly adopts technologies and methods long after they have become common in other sectors of the economy.

EDITOR: Are health plans and providers ready to move into the 21st century? The conflict between ever-lower payer pricing and the frustration of clinicians seems to be ongoing.

KAPLAN: Right now, there's a big disconnect between what's important to clinicians and what's important to payers. Healthcare is clearly moving in a direction of paying for performance and paying for responsiveness to the needs of patients. I stress this fact to all my clients.

EDITOR: But that trend is contrary to existing arrangements between payers and providers.

KAPLAN: Correct. Until now, most healthcare providers, including labs, have operated as if they were running a protected public

utility. If you're running a public utility, you have no reason to address market needs. You simply supply the service and collect your fees. But the market will change drastically over the next five to 10 years because of pressures building up within healthcare. These pressures include rising costs, reduced reimbursement, and increased demands for services from an aging population.

EDITOR: Lab directors and pathologists are familiar with all these issues.

KAPLAN: Recognize that these pressures are causing the healthcare system to both implode and explode at the same time. It guarantees we will have a different healthcare system in the future. That is why I advise my provider clients to prepare for this different future.

EDITOR: Looking at clinical laboratories, what steps do labs need to take to prepare for the future, particularly when contracting with health plans?

KAPLAN: It's simple. In the future there will be winners and losers. Labs that don't understand these changes and fail to change in fundamental ways will be the losers. Conversely, winning labs will understand the emerging value drivers in healthcare and evolve to meet those needs.

Kerry Kaplan

➤**"...there is still an advantage for small labs. That advantage involves being a little more agile, a little more mobile, and a little more aggressive compared with national labs."**

EDITOR: You are talking about strategy and execution, and a willingness to adapt to healthcare's evolving needs.

KAPLAN: That is easy to say, but it is difficult for laboratory organizations to implement. Last year (May 2007) at the *Executive War College*, Dave King, the CEO of **Laboratory Corporation of America**, explained how and why LabCorp was among the winners in the lab marketplace. Fundamentally, King was noting that the success of LabCorp involved thinking strategically and then putting the resources behind those strategies in each and every market in which they serve.

EDITOR: Certainly, LabCorp's 10-year exclusive contract with **UnitedHealthcare** was a strategic business initiative. It caused widespread ripples in the laboratory marketplace status quo.

KAPLAN: Yet, one lesson from King's presentation is that there is still an advantage for small labs. That advantage involves being a little more agile, a little more mobile, and a little more aggressive compared with national lab companies.

EDITOR: Can you explain how labs can be more agile, mobile, and aggressive?

KAPLAN: To be more agile, mobile, and aggressive requires thinking strategically and then executing that strategy, just as LabCorp works to do this on a national level. In reality, succeeding in any healthcare market requires effort to develop a comprehensive growth plan (a strategy) and commitment to stay with that plan (putting the resources in place to support that strategy). It also requires a certain level of sales and marketing expertise. So, if your lab doesn't have this expertise, you might want to hire someone who does.

EDITOR: How do you recommend laboratories develop a winning strategy as our healthcare system transforms itself?

KAPLAN: When it comes to health plans, my advice is to develop a multi-payer sales plan. Laboratories need a plan for each individual payer in their community with which they want a working relationship.

EDITOR: Why would a lab not want to work with a health plan in their region?

KAPLAN: One reason is that certain payers may not pay enough for laboratory testing services. Or they may not reimburse quickly. Whatever the reason, don't feel compelled to work with every health plan. Just focus on the plans with which your lab wants to work.

EDITOR: How should a laboratory develop this strategy?

KAPLAN: My multi-payer strategy has three steps. Each step involves analyzing your lab's internal resources and using your internal resources to meet your customers' needs.

EDITOR: What is step one?

KAPLAN: Step one is to identify the health plans in your market with which you want to work. In most markets, there's a Blues health plan, a for-profit plan, such as **Aetna**, **Cigna**, or UnitedHealth, and there may be a local or regional plan.

EDITOR: Once the lab has identified the target health plans, what is the next step in developing the strategic sales plan?

KAPLAN: Step two is to identify four key individuals in each health plan on your target lists: the CEO, the COO, the medical director, and the head of large case management. It is essential that you meet these executives and get to know them personally.

EDITOR: Often it is quite difficult to get appointments with these people.

KAPLAN: True. However, now it's time to do some creative networking. Find out who within your organization knows these people and how you can make connections with them. Send a list out to your employees and ask who knows them. Do you know them from church, the kids' sports leagues, and do they live in your neighborhood, for example? Your goal in finding out who knows these executives is to develop a relationship that involves more than just being a vendor of a commodity.

EDITOR: That seems simple enough. In other words, you're using your lab's internal resources to foster an external relationship. Is that right?

KAPLAN: Exactly. And that leads to step three. In this step, the lab director or lab CEO tailors a business strategy that addresses the unique needs of each targeted health plan. This strategy is the heart of your lab's multi-year sales plan. Now you can see why a multi-year sales plan can also be called a partnership. It's a partnership, because you're developing a relationship with each health plan to deliver the best health care to patients at the best price, and your aim is to do it over several years.

EDITOR: It can be quite time-consuming for the lab's leadership to cultivate these personal relationships.

KAPLAN: This does take more effort up front if your laboratory does not have existing relationships with the four executives from each targeted payer. However, once you've built these bridges, and have a true partnership, you'll be working together and meeting frequently. So, you'll know the specific needs of each of your health plan partners.

EDITOR: What you describe is quite different than how most regional or local laboratories currently handle their managed care relations.

KAPLAN: I would respond by saying that the failure to build these partnerships is one reason so many local labs find themselves excluded from important managed care contracts—and why they are frequently offered pricing that treats lab testing as a commodity.

EDITOR: That's true because most labs don't understand the unique needs of payers in their communities. Therefore, they do not offer services for which the payer is willing to offer higher reimbursement.

KAPLAN: This is where the partnership approach pays off. And don't forget—developing a multi-year strategy and sales plan involves meeting a number of needs at once for each payer on the target list. It's not a strategy of bidding one penny less per member per month than your competitor bids for each payer's book of business. Rather, it is determining the specific needs of the health plan to which your laboratory can provide a solution. And, you may be surprised to find that most labs currently do not deliver what plans

want. That was clear to me from the survey we conducted.

EDITOR: What are the most fruitful sources of added-value to payers?

KAPLAN: Lab directors should ask of health care payers, 'What are your major cost concerns over the next 18 to 24 months?' And, 'What can laboratories do to help you address these concerns.' The responses that we got from our survey of health insurance executives are examples of what a lab director will hear and it will vary by payer.

EDITOR: With the emphasis on improving healthcare outcomes, is there an effective way for labs to learn what clinical objectives have greatest priority with a payer?

KAPLAN: That's a sweet spot for a lab to bring value to the payer. I advise labs to have a clinician, such as a pathologist or Ph.D., present when getting the answers to these questions. By necessity, if I were a lab director, I would need someone on my relationship development team who is a clinician. That way, when I meet with the medical director or the large case manager, the clinician on my team can interpret what the medical director or case manager needs from the lab. That is a key. Remember that the sales manager has very specific skills, and that's different expertise compared with someone trained in medicine. To compete effectively and build that win-win relationship with health plans, your lab needs that extra level of clinical expertise.

Kerry Kaplan

➤ **"Lab directors should ask of health care payers, 'What are your major cost concerns over the next 18 to 24 months?'"**

EDITOR: This seems a bit obvious, so won't some labs grouse that what you're saying is basic marketing and sales communication 101?

KAPLAN: Yes, they may say that. But remember, the more thorough and sophisticated your execution of this strategy, the more likely you are to match your lab's services to the most important needs of the health plan. It generally takes diligent research and lots of effort. Further, by following these steps, you will do the classic SWOT analysis of your laboratory. You will do a thorough assessment of your strengths, weaknesses, opportunities, and threats. Even though these steps seem preliminary and perhaps obvious to some, they are absolutely critical to success in competitive markets. And that's what we have today: highly competitive healthcare markets. As I said earlier, we are no longer operating as a protected public utility.

EDITOR: Most laboratory management teams don't take the time to do this type of analysis as part of their managed care contracting effort.

KAPLAN: And look at the outcome. Too often, local laboratories are excluded from important managed care contracts in their communities. By doing an internal and external assessment, you identify that your laboratory is capable of meeting the needs of the key payers on your target list. These capabilities are what you leverage with the health plan to be a valued provider and earn better reimbursement.

EDITOR: Your common theme here is that laboratories should take the effort to offer a health plan more than simply lowest price.

KAPLAN: Generally, regional labs do not have the same economies of scale as the national laboratories have. So competing on price is going to be a losing strategy for most local laboratories. On the other hand, by matching your lab's capabilities to the health plan's unmet needs, you can develop and implement a multi-year sales plan that transitions you from being a commodity vendor to being a commodity vendor plus a partner with selected payers in your market. Being a commodity ven-

Health Plan Executives and Survey Questions They Answered About Laboratory Test Services

TO PROVIDE LAB DIRECTORS AND PATHOLOGISTS WITH INSIGHTS about how the health insurance industry views laboratories and diagnostic testing, Kerry Kaplan, President of Healthcare Connections, a healthcare consulting firm, in Natick, Massachusetts, interviewed nine managed care executives.

Each was asked three questions about how clinical labs can meet the needs of health plans more effectively. In a presentation to the Executive War College on Lab and Pathology Management last May in Miami, Florida, Kaplan shared his findings. This interview was based on that presentation and a follow-up discussion with Kaplan.

These nine executives were surveyed:

- Jack Friedman, CEO, Providence HealthPlans, Portland, Oregon
- Greg Culley, M.D., Medical Director, Capital Blue Cross, Harrisburg, Pennsylvania
- Mary McWilliams, CEO, Regence, Seattle, Washington
- Mike Cropp, M.D., CEO, Independent Health, Buffalo, New York
- Pam Kalen, VP, National Business Group on Health, Washington, D.C.
- Dwight Brower, M.D., Medical Director Blue Cross Blue Shield, Baton Rouge, Louisiana
- An unnamed former Wellpoint Executive, Richmond, Virginia
- Dennis Batey, M.D., CEO, Presbyterian Health Plan, Albuquerque, New Mexico
- Lee Newcomer, M.D., Senior V.P. of Oncology, UnitedHealthcare, Minneapolis, Minnesota

These three questions were asked: (The interviews were done either face-to-face or over the telephone.)

1. What are your major cost concerns over the next 18 months?
2. What is the status of evidence-based medicine now and in the future?
3. What is your advice to laboratories?

dor plus a partner will help you to work with health plans to reduce healthcare costs and improve quality. That's your goal: reduce costs and improve quality, and get paid more when you do.

EDITOR: Essentially, you're saying that labs need to adopt the goal of the entire health system: reduce costs and improve quality. Is that correct?

KAPLAN: Health plans are interested in both controlling costs and improving quality. They might be more interested in reducing costs today, but improving quality is becoming more important than it was a decade ago. And pressure for health plans to contribute to improving quality will increase steadily going forward.

EDITOR: Kerry, we need to stop here. In our next discussion, will you address specific ways that these health plan executives identified as ways for laboratories to add value to payers and earn additional reimbursement?

KAPLAN: Yes. We can discuss specific strategies that laboratories and pathology groups can use to shift contract negotiations away from "lowest price." Also, I have recommendations about how laboratories can use evidence-based medicine (EBM) and genomics to their financial benefit in managed care contracting discussions.

EDITOR: That promises to be useful information for our clients and readers.

KAPLAN: Good. Stay tuned, everyone. What comes next has lots of power and potential for labs to turn the tables on health plans! TDR

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CMS Anti-Markup Rules Target In-Office Ancillaries

➤Changes ahead for specialist doctors using TC/PC arrangements or operating AP labs

➤➤CEO SUMMARY: Medicare officials are again attempting to rein in what they consider to be potentially abusive forms of in-office ancillary services, including anatomic pathology. Proposed new rules published this month would clarify and perhaps expand the application of the Medicare anti-markup for purchased diagnostic testing services and for diagnostic tests provided by an ordering physician or supplier, including the professional and technical components.

AS EXPECTED, FEDERAL HEALTHCARE OFFICIALS are again tinkering with anti-markup rules. Their latest effort is directed toward curbing arrangements where physicians profit from purchased diagnostic testing services generated by their patient referrals, including anatomic pathology services.

New proposed revisions to the Medicare anti-markup rules were included in the *Medicare Part B Physician Fee Schedule (PFS) Proposed Rule for Cal-endar Year 2009*. This was published by the federal **Centers for Medicare & Medicaid Services** (CMS) earlier this month. The public comment period ends on August 29, 2008. CMS will respond to public comments and expects to publish the final rule by November 1, 2008. The final rule likely will become effective on January 1, 2009.

"If approved, these rules would extend to all purchased diagnostic testing services," observed attorney Jane Pine Wood, of **McDonald Hopkins**, a national law firm. "Anti-markup provisions would apply to both the technical component (TC) and professional component (PC) of diagnostic testing.

"Currently, the Medicare anti-markup rules apply only to anatomic pathology services," added Wood. "However, on January 1, 2009, published rules take effect that will apply anti-markup rules to all diagnostic testing services. CMS recognizes that the language of these existing anti-markup rules is somewhat ambiguous in actual application to particular billing situations. CMS hopes the newly-proposed rules will provide greater clarity.

➤Two Alternatives

"The government is requesting comments on two different ways to apply anti-markup rules," explained Wood. "The first alternative focuses on whether the physician or supplier who performs or supervises the diagnostic testing services shares a practice with the billing physician or supplier organization on a *substantially exclusive* basis. The other alternative focuses on the location *where the diagnostic testing services are performed.*

"The text of the proposed revision to the anti-markup rule," she continued, "provides that the diagnostic testing service *would not be subject* to the anti-markup restriction if: 1) service is performed and supervised within the office of the billing physician or supplier; 2) if the supervising physician is an employee or independent contractor of the billing physician or other supplier; and 3) if the supervising physician provides services *exclusively* for such billing physician or supervisor.

Anti-Markup Rules

"What's interesting is that CMS is squeezing down on the potential for overuse of diagnostic testing services, particularly anatomic pathology testing and imaging services," stated Wood. "These proposed rules seem to be intended to expand the range of services that would be subject to the anti-markup rules.

"If approved, these rules would not prohibit anyone from providing these services," she noted, "but they would mean that, when providing diagnostic testing for Medicare patients, the anti-markup rules would apply more broadly than they do now—in *any situation* where the supervising or performing physician *does not work exclusively* for the billing physician or supplier.

"If implemented as now written, these new rules will likely limit the profit margin on the provision of pathology services and other diagnostic testing services currently provided under the Stark exception for in-office ancillary services," Wood added. "That is the reason pathologists should study these proposals and take the opportunity to submit comments to CMS. The comment period ends on August 29.

"No one knows precisely how the final regulations will be worded," she said. "It is clear that the likely effect of these regulations, as written now, will be to make it more difficult for specialists to achieve a profitable in-office pathology arrangement. From that perspective, many pathologists will welcome the proposed anti-markup rule.

"As pathologists know, the anti-markup rule put in place on January 1, 2008, restricts mark-ups for anatomic pathology (AP) services for Medicare patients when those services are done off-site from that physician's office," she explained. "Since January 1, 2008, a urologist or a gastroenterologist cannot markup the cost of AP services if the work is done in a laboratory outside of the urology or GI practice, for example. This restriction covers AP condo/pod laboratories. The new proposed regulations would take the anti-markup concept to the next step.

"Under the proposed alternative, CMS would not prohibit anyone from doing work in their own in-office laboratory. But it would expand the circumstances where the anti-markup rule applies," stated Wood. "For example, the proposed regulations would not permit a mark-up by a urology or gastroenterology (GI) practice on services supervised or performed by a pathologist *who works for more than one practice* (including his or her own pathology practice).

Favorable to Pathologists

"Thus, if the physician group wants the ability to mark up the costs when billing Medicare for the anatomic pathology services, it means the pathologist performing the professional interpretations *cannot work anywhere else*," she commented. "That pathologist must work exclusively for the ordering practice for the practice to bill Medicare at the full rate for the interpretations.

"In addition, CMS also would apply this same rule to the supervision of technical component (TC) services. Thus, the group could only bill TC at the full rate if supervision is done by a physician employed exclusively by that group.

With Its Proposed New Anti-Markup Rules, CMS Puts TC/PC and In-House Ancillary Services on Radar Screen

IN A PUBLIC STATEMENT POSTED ON ITS WEB SITE, the Centers for Medicare & Medicaid Services (CMS) identified issues that the proposed new anti-markup rules would address. The statements make it clear that CMS is intent on reining in in-house ancillary services, such as anatomic pathology and imaging. Below are the summary statements of these points as provided by CMS:

- *Clarify that the "office of the billing physician or other supplier" includes space in which diagnostic testing is performed that is located in the same building in which the billing physician or other supplier regularly furnishes patient care;*
- *Clarify that, with respect to TCs, the anti-markup provision applies if the TC is either conducted or supervised outside of the office of the billing physician or other supplier;*
- *Clarify that a TC of a diagnostic test is not purchased from an outside supplier if the TC is supervised by a physician located in the office of the billing physician or other supplier;*
- *Clarify that, for purposes of applying the payment limitation in 42 CFR 414.50(a)(1)(i) only, the "performing supplier" with respect to the TC is the physician who supervised the TC and, with respect to the PC, the "performing supplier" is the physician who performed the PC; and*
- *Propose an exception for diagnostic tests ordered by a physician in a physician organization that does not have any owners who have the right to receive profit distributions.*

CMS also solicits comments regarding:

- *Defining the "net charge;"*
- *Whether, in addition to or in lieu of, the anti-markup provision, CMS should prohibit reassignment in certain situations and require the physician supervising the TC or performing the PC to bill Medicare directly; and*
- *Whether CMS should delay, beyond January 1, 2009, the effective date of certain anti-markup provisions published in the MPFS final rule for 2008, or delay the effective date of any proposed revisions to that rule, to the extent they are finalized in the MPFS final rule for 2009, or both.*

Web link: http://medicareupdate.typepad.com-/medicare_update/2008/07/cms-addresses-a.html

"This aspect of the anti-markup rule is a significant change," explained Wood. "Take the example of a urology group that wants to bill at full rate for the pathology services provided to Medicare patients. Either the group must have enough work to employ the pathologist full time, or, the group must use a part-time pathologist who does not work for any other practice."

As Wood points out, the new anti-markup rules proposed by CMS earlier this month definitely target in-office ancillary services and TC/PC arrangements. Since this is the second consecutive year that CMS has written proposed rules to apply anti-markup statutes to these activities, it is unlikely that public comments will cause CMS to soften or alter these rules in any tangible manner.

However, because so many specialists now view anatomic pathology services as a lucrative ancillary service, the pathology profession can expect continued efforts by these physicians to capture AP revenues to their personal benefit. **TDR**

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last Monday, **UroPath, Inc.**, an Arlington, Texas, company operating anatomic pathology laboratory condominium complexes in several states, disclosed its sale to **HealthTronics, Inc.**, of Austin, Texas. Sales price was $7.75 million. UroPath's former owners are urologists who founded the company in 2003. *(See TDR, August 9, 2004.)* HealthTronics sells and maintains lithotripters, laser products, and consumables to the urology professions. It also owns **Claripath Laboratories**, an anatomic pathology company in Augusta, Georgia.

MORE ON: UroPath

UroPath's sale to HealthTronics is likely to be in response to Medicare anti-markup rules that became effective on January 1, 2008. These rules prevent anatomic pathology (AP) condo/pod labs like those operated by UroPath from marking up claims to Medicare. UroPath and several related parties sued the Medicare program earlier this year to challenge the anti-markup rule. A federal judge ruled against UroPath and dismissed the case on May 6, 2008. UroPath says that, last year, its AP labs processed about 400,000 specimens for more than 50 urology practices employing 450 urologists in 17 states.

GENOME PROJECT ADDS 3 COMPANIES

Three companies that pioneered gene sequencing technologies have joined the 1000 Genomes Project, an international effort to build a detailed map of human genetic variation for research. The companies are: **454 Life Sciences**, a **Roche** company in Branford, Connecticut; **Applied Biosystems**, an **Applera Corp.** business in Foster City, California; and **Illumina Inc.**, in San Diego, California.

TRANSITIONS

• Christopher S. Frings, Ph.D., died at the age of 67 on July 3, 2008. A resident of Birmingham, Alabama, Dr. Frings was a regular on the national lab speaking circuit and had been honored in each of the past 20 years with an outstanding speaker award by the **American Association for Clinical Chemistry**. After receiving a Bachelor's degree from the **University of Alabama** and a Ph.D. in Clinical Chemistry from **Purdue University**, Dr. Frings completed a post-doctoral fellowship at the **Mayo Clinic**. It was in 1987 that he became a full-time consultant and speaker.

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…why Big Pharma is soon to crowd into the laboratory testing marketplace. The need for companion diagnostic tests for new therapeutic drugs and control over the bio-marker pipeline are behind this trend.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, August 18, 2008.

It's New!

PREVIEW #2

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UPMC Builds "Smart Hospital Rooms" Informed by Toyota Quality Methods

UPMC has created "smart patient rooms" with the goal of improving patient safety and the quality of care. As physicians and nurses enter the room, they are recognized and a bedside monitor cues them on what they need to know at that moment to care for the patient, including medications, allergies, and vital signs. At the same time, patients can view a second monitor to learn the identity and role of the caregiver who just entered the room, along with the schedule for pain medication and other relevant data. Learn how advanced technology and integrated health informatics are coming together with Lean methods to create an entirely new care paradigm.

For program details and to register:
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UPCOMING...

- ***Part Two: How Labs Can Build Added Value Relationships with Payers and Improve Pricing.***
- ***Why Your Laboratory May Not Want to Invest in a Regional Health Information Organization.***
- ***First News of Three Labs Racing to Be First to Earn ISO:15189 Accreditation in the United States.***

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