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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lab Test Methodology and Widespread EMR Use

IN BIRMINGHAM, ENGLAND, LAST WEEK to participate at the *Frontiers in Laboratory Medicine* (FiLM) conference, Editor Robert Michel picked up an interesting theme that connects to current laboratory events here in the United States.

"General practice (GP) clinics in England are establishing electronic medical record (EMR) systems as a preliminary step toward the goal of a national patient health record (PHR)," explained Michel. "Consequently, pathologists and clinical biochemists who run the nation's laboratories are beginning to foresee how one longstanding practice in laboratory medicine has the potential to create confusion among physicians and patients.

"In each city across the country, individual laboratories have always selected their test methodology, then used specimens collected from local residents to validate the test and develop reporting ranges," he continued. "Now, some lab professionals realize that, when a national patient health record becomes a reality, the individual patient's record will contain lab test data produced by several different labs. Because of different methodologies and different reporting ranges for the same test, they can foresee how physicians and patients, as they consult the individual's electronic medical record, will find the presentation of these cumulative lab test results to be confusing and not easy to understand. This realization by forward thinkers in the laboratory profession is causing some to predict that greater standardization of test methodology and reporting guidelines across all laboratory sites will need to occur as a consequence of a single national system of electronic medical records."

Michel's observation about this development in the United Kingdom has a parallel here in the United States. Wider adoption of a universal patient health record that is transportable across different providers, hospitals, and health insurers will raise the same issue in this country. The explosion of interest in Vitamin 25(OH) D testing may provide our health system with a first example of the problem generated by the use of different test methodologies. Today, different labs are using different methodologies to test for Vitamin 25(OH) D. They use locally-collected specimens to establish reporting ranges. This means that clinicians and patients, looking at Vitamin D results from different labs, cannot automatically assume that one lab's result means the same as another lab's result. Evidence exists that this situation has caused confusion among some physicians and patients during the past two years—a time when interest in Vitamin D testing grew dramatically. TDR

When Does Cost Cutting Affect a Lab's Quality?

Pathologists understand that any lab's quality and performance requires a careful balancing act

CEO SUMMARY: Many lab professionals note the irony that a laboratory so publicly committed to Six Sigma quality management methods is now identified with the single largest episode of systemic failure in lab test accuracy. Looking in from the outside, some pathologists suggest that a decade of aggressive cost cutting and the current campaign to remove another $500 million of costs in 36 months, may be a contributing factor in the 18-month period of systemic deficiencies.

FOR A COMPANY that consistently brags to Wall Street and the public of its Six Sigma prowess and how that translates into quality in lab test accuracy and service execution, the first weeks of 2009 have been an unpleasant taste of a possible new reality for **Quest Diagnostics Incorporated**.

Should future developments validate that a new reality exists, then there will be interesting ramifications for the entire clinical laboratory profession in the United States. Lab administrators and pathologists should be alert to these consequences.

For the nation's largest lab company, 2009 opened with a firestorm of media reports and public reaction to Quest Diagnostics' acknowledgement that it had reported inaccurate Vitamin 25(OH) D results for an 18-month period on tens of thousands of patients. *(See TDR, December 22, 2008.)* The question is: does this systemic testing failure of an internally-developed assay, run in a high volume setting, represent just a tarnish in the Six Sigma armor so proudly worn by Quest Diagnostics in recent years? Or, are the revelations about ongoing problems in its Vitamin D testing program a major chink in that armor—a first public hint that an operational tipping point may have been reached?

After all, Quest Diagnostics, with revenues of $6.7 billion in 2007, is currently in the midst of a widely-publicized three-year effort to eliminate $500 million in costs by the start of 2010. That's 13.4% of 2007's total revenue. Moreover, this is just the latest and biggest cost-reduction effort enacted by Quest over the past 11 years.

Has budget-cutting at Quest Diagnostics possibly reached a point where it constrains the ability of its technical team to perform the pre-analytical and analyti-

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

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cal stages and achieve a consistently superior analytical result—a lab test result which is accurate to the full potential of the diagnostic technology?

Lab Quality Requires Money

Pathologists, Ph.D.s, and laboratory scientists know an immutable truth about lab test quality. It takes money and resources to produce high quality lab test results which are the product of a careful execution of all protocols in specimen collection, specimen transport, specimen preparation, and specimen analysis. Skimp on any single step in the process, and the integrity of the result can be compromised in minor and major ways.

This is the financial quandary that confronts laboratory scientists every day in every laboratory across the globe. They understand the requirements and protocols that must be performed on every specimen and across all the different types of laboratory tests to ensure high quality, reliable results. At the same time, they recognize that their lab's budget constrains additional steps that would increase reliability of the test result. They also know that the training and experience of their staff plays an essential role in achieving high quality in their laboratory.

Specimen Integrity

Similarly, when phlebotomists collect the specimen; when couriers transport the specimen; and when accessioning receives the specimen and preps it for the testing bench—within each of these steps exists many opportunities to either compromise specimen integrity or enhance the specimen for the analytical stage. In other words, a specimen can be compromised if the worker lacks proper skills and experience, or is overworked and tempted to take shortcuts. Alternatively, skilled staff members, given adequate time to do their job with each specimen, can play a major role in delivering a superior quality specimen to the testing bench.

Simply put, a high quality, reliable lab test result requires sufficient funding, a trained and capable staff, with adequate manpower to properly handle every specimen during each shift. The other requirements are properly-maintained equipment, plus reagents and consumables that are of acceptable quality to properly perform the assay. Give short shrift to any of these variables, and a laboratory will lack the inputs required to practice a high quality of laboratory medicine.

Now the public knows that Quest's internally-developed home brew assay failed, for a period of one and one half years in clinical use, to produce accurate, trustworthy results at the standard expected by the profession and the public. Thus, Quest Diagnostics set itself up to be asked one big question: "How did this happen?"

Relentlessly Cutting Costs

Across the lab industry, some pathologists and lab professionals think they know part of the answer. They believe that relentless cost cutting in the public laboratory companies has reached the point where the integrity of lab test results could be threatened. One pathologist told THE DARK REPORT, "Since the day Quest Diagnostics became an independent company under then-CEO Ken Freeman in 1997, cost cuts have been non-stop. That's 11 years of taking money out of their operation. At some point, economic constraints mean that Quest is likely to cross the line where, instead of trimming fat, it cuts muscle, tendons, and bones."

This pathologist has the same source of intelligence on what is unfolding at the national lab companies as many other pathologists. Her lab regularly interviews the best and lesser-skilled med techs from the two blood brothers. Reportedly, the best MTs leave because they are discouraged at the working environment. MTs with lesser skills are regularly laid off in each regular wave of RIF (reduction in force) and they have their own stories to tell.

Labs Have Limited Capability to Swiftly Ramp Up Capacity to Handle Increased Volumes of Tests

ONE ASPECT OF THE VITAMIN D STORY at Quest Diagnostics is the role that capacity constraints might have played in its ability to cope with the huge ongoing surge in the volume of Vitamin D specimens which needed to be tested.

In early 2007, as Quest Diagnostics moved its home brew mass spectrometry Vitamin 25(OH) D assay into widespread clinical use, it may have been performing between 125,000 to 150,000 tests per month. This volume is believed to have tripled, reaching 500,000 tests per month by the summer of 2008, just 18 months later.

Here is where Quest Diagnostics' success at precisely aligning capacity to demand in its lab network may have worked against the company. At laboratories where little excess capacity exists, staff works at full productivity to handle the daily routine. This increases the average stress level of staff, particularly compared with many hospital labs nearby (a source of alternative employment and offering mostly day-shift positions). It also means that disruptive events to the daily routine often have disproportionate consequences, since the available staff has no additional time to divert and respond to unexpected events, including a steady growth in demand.

In the case of Quest's mass spectrometry Vitamin D program, if it was staffed adequately to handle, say, 150,000 tests per month, then significant month-to-month increases in specimen volume would quickly put that infrastructure of staff and analyzers into a high stress situation.

Moreover, as existing capacity is swamped by the rapidly increasing number of Vitamin D specimens coming in the door, Quest Diagnostics would run up against the capacity expansion constraints familiar to every laboratory. First is equipment. Even if new analyzers can be obtained quickly, it can often take weeks and months to properly calibrate a new instrument and validate its performance before using that analyzer for clinical services.

Then comes the need for staff. Hiring enough med techs with the proper skills is always challenging, but often impossible in tight labor markets. This would be a daunting limitation for Quest Diagnostics. Already employing probably the largest number of Ph.D.s and med techs skilled in mass spectrometry in the United States in its regular mass spec testing program, including, say 150,000 Vitamin D specimens per month, how would it be able to hire enough proficient laboratory scientists at a pace which would allow it to stay current with the growth to 500,000 Vitamin D specimens per month? That would be tripling the mass spec testing staff in just 18 months!

These assessments show how the sheer size of the nation's largest laboratories create barriers to swiftly responding to major increases in test volume in short periods of time. If Quest's mass spec Vitamin D program was at full capacity at 150,000 tests per month in early 2007, then a tripling of specimen volume in only 18 months would create significant pressure and stress on both the available instrumentation and technical staff.

This is an information pipeline that has functioned for years and is one reason why pathologists in competing labs are aware of how unrelenting waves of cost cutting programs at both the national labs affects staff morale and continually erodes the capability of these lab companies to sustain a superior level of quality in their test results.

Quest Diagnostics' new reality may be that, following its decade of aggressive cost cutting, it has finely-tuned its capacity to meet expected volume. Unexpected disruptions to the status quo leave this company with less flexibility to respond. Thus, problems with its Vitamin D testing may be a first public notice of this development. TDR

Laboratory Industry Has "Elephant in the Room"

In January, a major lab failure was national news, but the story went unremarked by most lab sources

CEO SUMMARY: In almost every laboratory across the United States and in several countries around the globe, one much-discussed topic in recent weeks has been the Vitamin D testing program deficiencies at Quest Diagnostics Incorporated. Yet, even as rank and file laboratorians actively talked to each other about what this story means, the lab industry's professional associations, societies, and publications were silent on this matter, with few exceptions.

As NEWS OF WHAT MAY BECOME KNOWN as the "Vitamin D testing fiasco" made headlines across the nation last month, there was near total silence from the clinical laboratory profession.

First, outside of pathologists and executives employed by **Quest Diagnostics Incorporated**, no news stories known to THE DARK REPORT carried quotes, opinions, or information credited to a pathologist, laboratory scientist, or laboratory executive. That is a meaningful fact.

Second, even weeks after the national news stories made the American public aware that Quest Diagnostics had reported inaccurate Vitamin D test results on tens of thousands of patients during an 18-month period during 2007 and 2008, this story remained virtually unreported and unmentioned by laboratory associations, professional societies, and laboratory industry publications—with three exceptions.

These three exceptions were THE DARK REPORT, which was first to print the story about Quest Diagnostics' systemic problems with Vitamin 25(OH) D testing and its voluntary program to notify and offer free retesting to what may be as many as 490,000 patients; *Clinical Lab Products* (CLP) magazine, which immediately posted the news on its Web site; and *Laboratory Economics*, which published its analysis of the story in its very next issue.

This raises an interesting question. Why did the national media recognize the significance of a major failure by a respected lab company to report accurate test results to huge numbers of people—even as the lab industry's usual sources of news, current events and industry gossip chose to not provide this same news story to their members, readers, and audiences?

Ignoring The Big Story

What does it mean when the laboratory profession's leading institutions go about their business as if nothing happened? Meanwhile, newspapers and television reports are full of headlines such as "Quest Acknowledges Problem with Vitamin D Test" and "Lab Sent Out Number of Flawed Vitamin D Test Results."

This silence is certainly not an accident nor an oversight. Everywhere THE DARK REPORT has traveled since it broke this news, lab administrators, pathologists,

and medical technologists are quite familiar with the fact that Quest Diagnostics admitted it reported inaccurate Vitamin D results to a huge number of patients. In fact, these individuals have many questions and seem interested to learn more details about the nature of the problems, how Quest conducted its root cause analysis, and what it is doing differently to prevent such a systemic failure from recurring again.

Since the rank and file in laboratory medicine are keenly aware of this story and actively discussing it in their own laboratories, why are the industry's professional societies, associations, and most publications ignoring this unprecedented event in laboratory medicine? After all, keeping members and readers posted on important developments is one reason these organizations get support from laboratory professionals.

Two Common Responses

The deafening silence across this spectrum of the laboratory industry may turn out to be a significant outcome on its own. In polling pathologists, clinical chemists, and medical technologists about why they think their associations and societies have not posted any news bulletins or commentaries about this story, they express puzzlement about the lack of recognition and commentary about this event. Their responses follow two common themes.

Invariably, the first theme most mention is how the public disclosure of major systemic failures at the nation's largest lab company has the potential to trigger increased regulation that becomes a burden on the entire laboratory. Essentially, they are concerned that the sins of one lab will bring unwelcome consequences on the many.

The second theme, almost as common as the first, is that most lab professionals immediately recognize that those professional associations involved in licensing, inspections, accreditation, proficiency testing, and quality management activities may have much to lose. If laboratory regulators and elected officials were to dig deeper into the acknowledged deficiencies within Quest Diagnostics' Vitamin D testing program, these regulators may then turn their attention on how the oversight activities of the relevant lab associations failed to either prevent these deficiencies or catch them during the 18 months that Quest acknowledges it had systemic problems.

Out Of Step With Rank & File

This anecdotal survey of the lab industry rank and file seems to indicate that leaders in these professional associations are out of step with their members by not publicly recognizing the events surrounding Quest Diagnostics' acknowledgement of its Vitamin D testing program deficiencies.

This fits the metaphor of the elephant in the room. The elephant is so big, everyone knows everyone else sees it. Yet still, no one wants to publicly discuss the elephant until someone else goes first. Maybe this silence is because the laboratory industry was not ready to respond to news of a major failure by a major laboratory that affected tens of thousands of doctors and several hundreds of thousands of patients.

This lab failure is not the action of a single phlebotomist found to be reusing butterfly needles on her patients (**SmithKline Beecham Clinical Laboratories**–1999). Nor is it a rogue laboratory administrator who, for two years, actively suppressed the medical technologists in his lab from expressing their concerns about how the failures of a single instrument used in HIV and HCV testing was putting patients at risk. (**Maryland General Hospital**–2004.)

Rather, the lab industry finds itself confronting an unexpected reality: the profession's largest testing organization has failed on a scale never before seen in laboratory medicine. There seems to be no crisis plan at any major professional lab organization which can guide its leadership in making an appropriate public response. TDR

Quest's Deficiencies Trigger QA/QC Questions

➤Problems in test accuracy should be studied and relevant lessons shared with lab industry

➤➤CEO SUMMARY: Experts in laboratory QA/QC and proficiency testing (PT) are following the news that Quest Diagnostics admitted to an 18-month problem with lab test accuracy in its home brew Vitamin 25(OH) D assay. It is recognized as a major failure in the existing system of laboratory licensure, accreditation, and proficiency testing. However, to improve current lab quality standards, more needs to be known about how quality systems failed at Quest Diagnostics.

PATHOLOGISTS ACTIVE in laboratory quality assurance/quality control (QA/QC) organizations are beginning to react to the national headlines that **Quest Diagnostics Incorporated** was reporting inaccurate Vitamin 25(OH) D test results.

Two facts catch their attention. First, Quest Diagnostics has acknowledged that tens of thousands of patients and their physicians were given inaccurate results for Vitamin 25(OH) D. Based on what is known about Quest's Vitamin D testing program, THE DARK REPORT estimates that between 350,000 and 490,000 patients are involved in Quest's voluntary notification and retest program.

Second, Quest has publicly admitted that its Vitamin D testing program produced inaccurate results over an 18-month period, from early 2007 through mid-2008. It has told reporters that about 7% of the total Vitamin 5(OH) D tests performed during this time were inaccurate.

In terms of the number of patients affected, a laboratory quality management failure on this scale is unprecedented in the profession of laboratory medicine. Further, Quest Diagnostics is a lab company that builds its public image and branding around the twin themes of reliability and high quality, along with patient/physician trust in its accuracy. It has consistently touted its commitment to Six Sigma quality management methods as setting it apart from competing labs. These are additional reasons why deficiencies in its testing stunned the laboratory profession at large.

➤Important Questions

"From the laboratory QA/QC perspective, these public disclosures about a major failure in laboratory testing accuracy raise many important questions," stated medical microbiologist Michael A. Noble, M.D., FRCPC, Chair, Program Office for Lab Quality Management, **University of British Columbia** in Vancouver, Canada.

"In most North American and international laboratory quality commissions, agencies, and committees, Quest's problems with its testing program will be discussed and studied," predicted Noble. "After all, Quest Diagnostics participates in many of these quality management programs itself and was generally viewed as being a leader in laboratory test quality and integrity. So it

becomes a relevant goal for professionals in laboratory quality to do—if you will—their own root cause analysis. Were quality guidelines inadequate to prevent this situation? Alternatively, were there organizational dynamics within Quest Diagnostics that overrode the institutional quality management requirements?"

Noble has an interesting perspective on laboratory quality management. He operates an ISO 9001:2000 certified proficiency testing program for Canadian laboratories. For laboratory quality managers, he provides international proficiency testing training, as well as a university certification course. He is a member of Technical Committee 212 for the **International Standards Organization** (ISO). This body wrote the standards for ISO 15189: Medical Laboratories, as well as other ISO standards for *in vitro* diagnostics (IVD). He is active in laboratory quality programs supported by such agencies as the **Centers for Disease Control and Prevention** (CDC) and the **World Health Organization** (WHO).

"Many of us with a professional focus on laboratory quality management were disappointed to learn that Quest Diagnostics had admitted to these serious problems," observed Noble. "Besides the obvious consequences to Quest and its reputation with physicians and patients, this major failure in lab test integrity has implications for the design and adherence of existing laboratory quality systems, licensing, and proficiency.

Quality Oversight In Labs

"Important questions must be asked, both of Quest Diagnostics and those governing agencies delegated with quality oversight in laboratory operations and laboratory competence," added Noble. "Let me run through the key questions.

"Where were all the watchdogs tasked with insuring quality and integrity in clinical laboratories in the United States?" he asked. "There are multiple levels of authority that have a role in monitoring lab quality. These include CMS and the Medicare program, CLIA, CAP accreditation, and proficiency testing (PT).

"One starting point is how Quest Diagnostics validated its laboratory-developed test (LDT) for the Vitamin 25(OH) D assay," continued Noble. "There are clear, detailed standards. If Quest was following these standards, then why did its assay fail when introduced as a regular clinical service? Why did it take so long to respond to these testing concerns?

Lab Failures Affect Patients

"Most of the national news reports included recognition that these failures to provide accurate, reliable test results to physicians and patients had the potential to negatively affect patient care," declared Noble. "To its credit, the *New York Times* reporter did interview physicians on this point. The media plays an important role in promoting quality practices when it shines the light on events that can erode public confidence.

"Proficiency testing (PT) is my primary professional interest," said Noble. "PT testing is a major safeguard and guidepost to help a laboratory have confidence in the quality and integrity of its laboratory test accuracy. Once Quest Diagnostic introduced its home brew Vitamin D assay, how and why did its proficiency testing program fail to detect the problems in a timely fashion?

"Particularly troubling to lab quality assurance experts is the disclosure by Quest Diagnostics that its problems went on for at least 18 months," he stated. "Did their PT program fail to detect errors in Vitamin D challenges over that whole extended period? If so, we need to fix any weaknesses in existing PT standards.

"Alternatively, was the PT team at Quest Diagnostics swamped and overwhelmed by any or all of these factors: size of the Vitamin D testing program, its multiple testing sites, and the ever-increasing number of samples coming in each night?" asked Noble. "Of course, there could be other reasons why proficiency testing did not change the situation. For example, did the PT team hide

their findings or remain silent because of fear about the consequences of going on the record that a sizeable number of lab test results were inaccurate? Remember, proficiency testing is supposed to be the front line of quality for every accredited and licensed laboratory.

Accreditation And Inspection

"Another quality management aspect that should be scrutinized is the inter-site comparison, accreditation, and inspection process," added Noble. "Quest says it performed these Vitamin D tests at seven laboratory sites. It also said that four of these sites produced unreliable test results—at the surprising rate of 7% inaccuracy—over a period that extended to 18 months!

"Nearly all these seven laboratory sites were likely to have had their CAP (**College of American Pathologists**) accreditation inspections during that 18-month period," he said. "What happened during these inspections? Did the inspectors execute their responsibilities properly? On the other hand, what did the laboratory staff know about issues in the Vitamin D testing program? Was that knowledge communicated to the inspection team while they were on site?

"All laboratory professionals recognize that laboratory licensing, accreditation, and proficiency testing requirements are not perfect solutions to guarantee lab test accuracy and reliability," commented Noble. "However, it is the starting point to protect patients and provide quality lab test results to clinicians.

"Thus, when a significant quality failure like this surfaces, our profession needs to understand what worked and what didn't," he explained. "This is the scientific process. I would like to call upon Quest Diagnostics to share its analyses of its problems with this Vitamin D testing program with the laboratory testing profession. What are the lessons it has learned that need to be evaluated and incorporated by other laboratories?

"We know that every laboratory has errors and deficiencies. That is the underscored reality that necessitates the cycle of continual improvement processes," added Noble. "What is important is how the laboratory responds to those mistakes. Quest Diagnostics seems to have fulfilled its requirements to self-assess, correct its internal problems, notify physicians and patients who may have received inaccurate Vitamin 25(OH) D results, and retest those patients. It would be beneficial to the entire lab profession for Quest Diagnostics to share lessons. That would allow us in the quality management community to revise and improve guidelines and requirements in ways that advance lab quality and boost lab test integrity."

Noble also believes that the publicity about Quest Diagnostics' acknowledgement of inaccurate Vitamin D results may have another consequence for the lab industry. "In the United States, requirements for CLIA, Medicare accreditation, and state laws have already created plenty of fear in labs that they might lose their operating status were they to be truly forthcoming in acknowledging all the deficiencies that often occur in daily operations.

Gaming Quality Oversight

"Such a motivation already exists to game PT and accreditation inspections," explained Noble. "Now, recent widespread publicity about Quest's problems with inaccurate Vitamin D results adds to that motivation. Having seen the publicity blitz surrounding Quest's acknowledgement of its deficiencies, one consequence can be to make a laboratory more reluctant to self-disclose problems as it follows PT, QA/QC, and other quality requirements."

To date, no other pathologist or official involved in laboratory licensing, accreditation, and proficiency testing has made a public statement about this matter. Thus, it remains unknown as to what type of regulatory response may yet result. TDR

Contact Michael Noble, M.D., at 604-875-4685 or mnoble@interchange.ubc.ca.

Got a Lab Test Question? Call an ASCLS Lab Guru!

ASCLS service gets 115 queries every day, almost 42,000 a year—and patients love it!

CEO SUMMARY: Each year since its launch in 2001, the ASCLS Consumer Response Team serves increasing numbers of patients and physicians. Clinical Laboratory Scientist volunteers from the American Society for Clinical Laboratory Science provide answers and help patients understand the meaning of their lab test results. After sending a question by e-mail, these patients get answers within 24 hours. This non-commercial, peer-reviewed, patient-centered site is helping fill a gap in care delivery.

MOVE OVER "LAB TESTS ONLINE!" There is another big success story in how laboratory medicine serves consumers. It is the Consumer Response Team organized by the **American Society for Clinical Laboratory Science** (ASCLS) of Bethesda, Maryland.

ASCLS organized its Customer Response Team in 2001, in support of the "Lab Tests Online" (*www.labtestsonline.org*) Web site. Lab Tests Online was created by a consortium of lab industry organizations. It is a non-commercial, patient-focused site which provides information to patients about any and all clinical laboratory tests.

When visiting Lab Tests Online to seek information about the meaning of their lab test results, consumers have the option of sending questions to the ASCLS Consumer Response Team. On the Web site, there is detailed information about most laboratory tests. Prepared responses can be found for common questions. If the patient or consumer wants to submit a question by email, he/she will receive a response from a clinical laboratory scientist within 24 hours. Neither Lab Tests Online nor the ASCLS Consumer Response team accepts phone calls.

A team of 50 clinical laboratory scientist volunteers manages the Consumer Response service. These individuals work in a wide variety of fields in labs nationwide. The ASCLS says those answering the questions are some of the best and brightest lab scientists working today.

More People Visiting The Site

When the Lab Test Online Web site became active in 2001, consumer questions came in a slow trickle. However, the number of patients, physicians, and consumers visiting *www.labtestsonline.org* grew steadily. Currently, every day the ASCLS Consumer Response Team receives about 115 e-mail queries—almost 42,000 per year! Many of the same volunteers who started answering the questions in 2001 still do so today.

"In recent years, we've seen the number of questions increase steadily," said Susan J. Leclair, Ph.D., CSL(NCA), the Chancellor Professor in the Department of Medical Laboratory Science at **UMass Dartmouth** and the chair/leader of the

Consumer Response Team. "One reason for this increased activity is that patients are becoming more interested in their own care. Another reason is that the time physicians spend with patients has been cut sharply."

Doctors Submit Questions

Leclair is responsible for quality control at the ASCLS Consumer Response Team. In that role, she reads every question and every answer. Leclair says that it is not only patients who use the services of the Consumer Response Team. An increased number of physicians are submitting questions.

"This increase in provider e-mails came just within the last year," observed Leclair. "Previously, we got very few from physicians—maybe 1% or 2% of the total. Currently, questions from physicians now represent about 5% to 8% of our total.

"Questions from physicians tend to center around such topics as the complexity of testing, how to interpret results, the limits of some tests, the volume of testing, and recently introduced tests," she commented. "In general, the most common format for a question from a provider is first a thumbnail sketch of a patient and then a statement about test results that he or she does not understand.

Resource For Physicians

"Sometimes physicians ask about tests that are uncommon," she continued. "They want confidence in how to interpret the results. The high sensitivity c-reactive protein test is a good example because it is better than the sedimentation rate for evaluating inflammation. The doctor wants to know, 'How do I use this information?' Clinical practice is moving from a test (sedimentation rate) that was around for a very long time to a slightly newer, better, more specific test (c-reactive protein). Physicians want confidence that they are ordering the newer test appropriately and interpreting the results accurately.

"We are an adjunct to the more traditional way of getting information," Leclair said. "If a pathologist works an 8- or 10-hour day, he or she is likely not available at 10 p.m., just when a physician reviewing test results needs an answer. That's another aspect that makes the Lab Test Online service useful: It's available 24 hours a day.

"I believe two major forces drive the growing patient and provider interest in this service," she added. "First is the sea of change in the way patients look at healthcare, particularly in the United States. When our parents went to the doctor, they listened to what their doctor said and there was not much else to discuss.

"That rather passive nature of patients has changed," continued Leclair. "Starting in the 1990s, people began to tell their doctor, 'Don't just give me your diagnosis and treatment plan. You need to give me facts, figures, and support for everything you're telling me.'

Less Time With Patients

"Second, also in the 1990s, and predominantly in the United States, was the influence of managed care," Leclair explained. "As managed care attempted to cut costs, physicians found themselves with a limited amount of time to spend with patients. Now the average physician has only seven minutes with each patient. That's not enough time for a discussion about lab test results or any other aspect of patient care.

"This was also the time that patient support groups started forming on the Internet," she continued. "One of those groups was the **Association of Online Cancer Resources** (ACOR). It formed in the mid-1990s because patients were seeking more information than they could get from physicians.

"It was this type of patient for whom we designed the ASCLS Consumer Response Team," Leclair said. "One joke you will hear on ACOR is that the most

common ailment that cancer causes is deafness. This describes the reality of a patient at the time of an unwelcome diagnosis. When a patient hears the word 'cancer', they hear very little of what the physician says next.

"Then they go home and stew for a while," she stated. "But after 24 or 48 hours, they have many questions. So if the next doctor's appointment isn't for two weeks or two months, we can fill those information gaps for them. When their physician says something in 'medicalese' we can provide a translation."

Leclair says that patients from all around the world visit the Lab Test Online Web site and submit questions to the ASCLS Consumer Response Team. "It's possible to ask a question in Czech, German, Greek, Hungarian, Italian, Spanish, and Polish. We get the question translated and send an answer back in the native language," noted Leclair.

Most Frequent Questions

What questions are asked most frequently? "Biochemistry—including blood sugar tests and lipid studies for cardiovascular disease—probably make up the largest volume of inquiries," Leclair said. "We also get many questions about cardiovascular tests, such as blood cholesterol and lipoproteins. Questions come in about thyroid disease, HIV status, and hematology—particularly as it relates to anemia. Recently we've even seen a surge in questions concerning fertility studies and hormone levels."

While Leclair and the other volunteers can answer many different types of questions, some are beyond the reach of clinical lab science. Patients and physicians who ask such questions are referred to other sources.

"If any question is beyond our scope, I explain that the service is designed to help patients and others understand their laboratory test results," Leclair said. "If I know where they need to go, I will refer them to the appropriate clinician or other provider resource. Otherwise we just tell them to use Google or other general medical search sites and to be careful about what they read."

THE DARK REPORT observes that the ASCLS Consumer Response Team is one of the hidden gems of the clinical laboratory industry. It is a much-needed channel that allows consumers and patients to directly interact with laboratory medicine professionals. TDR

Contact Elissa Passiment at 301-657-2768 or elissap@ascls.org

Lab Tests Online Helps With Communication Gap

BRIDGING GAPS IN COMMUNICATION between physicians and their patients is a common service provided by the Customer Response Team, the Internet information service managed by the American Society of Clinical Laboratory Services (ASCLS).

"Often, physicians explain things using a medical shorthand that patients don't understand," said Susan J. Leclair, Ph.D., CSL(NCA), the Chancellor Professor in the Department of Medical Laboratory Science at UMass Dartmouth and a volunteer at Lab Tests Online.

"A patient can have an abnormal complete blood count, for instance, and the physician will get the result and say, 'Fine,' and then tell the patient to take iron pills. That's a common example", observed Leclair.

"Then the patient will write to us and ask, 'How can my physician say, 'Fine,' when I have these unusual ranges?' What the physician meant was the lab test confirmed a diagnosis based on other information from the patient. Now the physician knows what to prescribe. In that sense, saying, 'fine,' is the physician's shorthand for verbalizing the entire thought process with one word. As clinical lab scientists, we can provide the translation."

Milestones

Staunch Laboratory Advocate Retires After 31 Years of Service

Joe Boone, Ph.D., stepped down last month from his position at CDC's Division of Lab Services

LAST MONTH, THE LABORATORY INDUSTRY lost one its most dedicated, full-time advocates. With his retirement in January, Joe Boone, Ph.D., ended a 31-year career with the **Centers for Disease Control and Prevention** (CDC).

Boone started with the CDC in 1977. In 1992, he assumed his present position as Associate Director for Science, Division of Laboratory Systems (DLS) at the CDC. During the past 17 years, Boone actively worked to advance the recognition of laboratory medicine. He advocated the more effective use of lab testing to achieve national and international health goals.

Joe Boone, Ph.D.

Boone has been a contributing member of work groups that include the **International Organization for Standardization** (ISO), the **Clinical and Laboratory Standards Institute** (CLSI), and the **Organisation for Economic Co-Operation and Development** (OECD).

Important Lab Guidelines

Boone participated in the development of several major international medical laboratory guidelines. Three examples are: CLSI's "Quality Management System for Healthcare"; the ISO 15189 "Medical Laboratories—Particular Requirements for Quality and Competence"; and international guidelines for quality assurance in molecular genetics testing.

Boone has a knack for bringing together national and international experts across many medical specialties. While at the DLS, he organized institutes on laboratory practices in 1989, 1995, and 2002. Starting in 2003, he led efforts at DLS to further the use of quality management philosophies and systems by laboratories in the United States.

First came the "Quality Institute" in 2003, followed by the "Institute for Quality in Laboratory Medicine (IQLM)" in 2005, and the "2007 Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health" in 2007.

Boone's effectiveness is based in equal measures on his personal integrity, his ability to build consensus across many stakeholders, and his commitment to excellence in laboratory testing services. His peers recognized these qualities, and he has received such recognition as the **American Association for Clinical Chemistry's** (AACC) award for Outstanding Clinical Laboratory Contributions to Improving Patient Safety (2005), and the A**merican Medical Association's** (AMA's) 2009 Dr. Nathan Davis Award for Outstanding Government Service (2009.)

In retirement, Boone plans to consult, as well as volunteer his services to professional organizations. With his energy and vision, it is likely that Joe Boone will make further contributions to the lab industry. TDR

Denver's UniPath Sells Its Histo Labs to APP

UniPath and American Pathology Partners announce a two-part business agreement

CEO SUMMARY: UniPath ended a long search for a business partner with ample capital and resources to help it continue its aggressive rates of growth in specimen volume, market share, and revenue. UniPath announced the sale of its technical laboratories to American Pathology Partners of Brentwood, Tennessee, along with a business agreement to provide pathology professional services. The agreement leaves UniPath in full control of its professional corporation.

IN RECENT YEARS, PATHOLOGY SUPER GROUP **Unipath, LLC**, of Denver, Colorado, has entertained a number of prospective buyers. Last month, it announced a combination sale and partnership with **American Pathology Partners, Inc.** (APP) of Brentwood, Tennessee.

There are two parts to this laboratory acquisition. In the first part, APP acquired the histology laboratory assets, namely UniPath, LLC. This includes the 40,000 square foot independent central lab in Denver and on-site laboratories in 11 hospitals in Colorado. The 120 employees working in these facilities are now employed by APP-UniPath, LLC.

Two-Part Transaction

In the second part of this transaction, UniPath's professional corporation (PC) entered into an agreement to cooperatively develop new business with APP and provide professional pathology services. Under this arrangement, UniPath's 25 pathologists maintain full ownership and control of their professional corporation.

"The purchase offer made to us by American Pathology Partners was fundamentally different than what we were offered from other interested buyers," stated Karim Sirgi, M.D., UniPath's President. "Other buyers wanted an outright purchase of both the technical laboratory facilities and the professional corporation.

"Then, after acquiring the professional corporation, these other buyers indicated that they would put the pathologists on salary," added Sirgi. "That would mean loss of pathologist control on many key professional matters. But in the deal with APP, the UniPath PC remains intact and all professional matters remain under the control of pathologists. That aspect of the deal was extremely important to us."

Under the business agreement between UniPath and APP, capital will be available to UniPath to fund expansion of business services and acquire new diagnostic technologies and lab equipment. APP will support a sales force that promotes UniPath's services in markets outside of Colorado.

UniPath has annual revenues of approximately $25 million. During 2008, UniPath handled 173,000 patient cases representing 363,000 specimens.

American Pathology Partners was formed last year with $75 million in funding from **New Enterprise Associates**, a venture capital firm in Chevy Chase, Maryland. Now that APP has its first lab partner in place, it intends to deploy its sales force to win new business for the UniPath venture in states west of the Mississippi River and possibly on the east coast as well.

Pathologists at UniPath faced a business dilemma common to many thriving pathology group practices: not enough business capital to sustain growth. "The goal behind the business transaction is to take us to the next level," Sirgi commented. "All our accomplishments over the past 12 years are a result of the physicians' direct investments in our lab, the equipment, the technology, and the hiring of subspecialists. UniPath was 100% internally financed and managed.

Required Additional Capital

"Finally, our company reached a point in its business life where, to reach the next level of growth and profitability, UniPath required a national partner with ample capital resources, as well as a different outlook on the national business landscape," he continued. "We recognize the need to continually add new molecular technology and support all the informatics and business services necessary for success in today's competitive market for anatomic pathology services."

UniPath's pathologists expect that APP will be the right catalyst to spark increased growth in market share, specimen volume and revenue. "As the first deal and the first large platform laboratory for APP, we hope a lot of opportunities come our way in terms of providing support services to other labs throughout the United States," said Michael Venrick, M.D., UniPath's Medical Director.

"We are already a big player in this part of the country, but there is room for expansion in terms of additional technologies that we don't currently offer," added Sirgi. "There are additional lines of business that we are not structured to offer at this time. We don't look at this partnership as a static business deal. We look it as a dynamic opportunity to propel us forward in our goals to expand in Colorado and beyond."

Moving To The Next Level

Venrick agreed, saying, "One motivating factor for UniPath's pathologist-shareholders was that it wasn't sufficient—and it wasn't interesting either—merely to merge or be acquired. We wanted an alliance or a partner who would help us move to the next level. We realized that we needed an influx of capital and business expertise that we didn't necessarily have. We also wanted help to move us into new territories and to help us develop new markets and new products. We are confident that APP is the right partner to help us achieve these objectives."

THE DARK REPORT believes this transaction between UniPath and American Pathology Partners is noteworthy. It is the first business deal for the fledgling APP, which became operational last spring. As long-time clients and readers of THE DARK REPORT know, from the mid-1990s forward, a steady progression of "pathology consolidators"—companies formed to acquire and operate multiple pathology groups—appeared. Most of these companies never gained traction and soon disappeared, generally by acquisition to larger lab company.

Enviable Growth Record

APP believes it has a different business model and it has certainly attracted a credible pathology super-group as its first business transaction. UniPath has an enviable track record of sustained revenue growth and market share gains. Now allied with American Pathology Partners, UniPath has the potential to become a serious competitor on a national scale. TDR

At UniPath, contact Tricia Hughey at thughey@unipathllc.com or 303-512-2202. For APP, contact Bob Yeager at 615-277-1410 or ryeager@americanpathpartners.com.

Did CMS Err in Issuing New Anti-Markup Rules?

CMS commentary creates uncertainty about whether technical component supervision is needed

CEO SUMMARY: In the latest anti-markup rules that took effect on January 1, CMS may have unintentionally stated that the anti-markup rule doesn't apply when a pathologist is reviewing histology slides. While the rule itself is unclear, the commentary that accompanies the rule says that supervision is not required. This ambiguity has been noticed by experts. It means that pathololologists, lab directors, and their attorneys must act carefully to ensure compliance.

DID THE FEDERAL **Centers for Medicare & Medicaid Services** (CMS) make a mistake when it issued its latest anti-markup rules?

According to Jane Pine Wood, a health law attorney with **McDonald Hopkins**, a national law firm, some health care lawyers have observed a discrepancy in new physician anti-markup rules which took effect on January 1, 2009. It appears that, unintentionally, CMS may have stated that the anti-markup rule doesn't apply when a pathologist reviews histology slides. Wood's colleague, Rick L. Hindmand, agreed. He notes that experts are asking questions about this aspect of the new anti-markup rules.

As with many CMS rules, the issue is complicated by several factors. First, the rule became effective on January 1 and so has been in place only a short time. Second, the rule-making staff at CMS recently experienced turnover when lawyers who drafted the new anti-markup rules went into private practice. Third, changing the rule could require a revision and a comment period, which could take a number of months at a minimum. In the meantime, there is uncertainty about CMS' intent under the new anti-markup rules.

"If you read the language of the rule—literally as it is currently written and in effect as of January 1—the anti-markup rule applies if the test is performed by a physician who does not share a practice with the billing physician or billing supplier," Hindmand said. "And, when it comes to the case of the technical component (TC), CMS defines a performing physician as a physician who *supervises* the technical component. So, if there is no supervision, it can be construed that this situation doesn't fall within this anti-markup rule because the test is not supervised by another physician.

Supervision at Issue

"Here's my understanding of the problem," he said. "Relevant language in the anti-markup rule statute applies to diagnostic tests which are: 1) not personally performed; or, 2) not supervised by either the billing physician or by another physician in the practice. The rule that took effect on January 1 applies the anti-markup restriction if the test is supervised or performed by a physician who doesn't share a practice. In its com-

mentary on this rule, CMS indicated that, if the procedure or test in question does not require supervision under Medicare standards, than the anti-markup rule doesn't apply.

"The commentary also indicates that CMS believes anatomic pathology was covered under the anti-markup rule," added Hindmand. "So there is essentially an open issue about whether the technical component (TC) is covered for anatomic pathology services. To the extent that the services don't require supervision, there is some uncertainty as to whether the anti-markup rule applies.

Arguments on Both Sides

"Knowledgeable people now argue that—as the rule is written now—the professional component (PC) of anatomic pathology may not be covered because of the way the rule and the commentary is drafted," he observed. "If the anti-markup rule doesn't apply, then clearly that would be a huge change.

"This change can be seen clearly when the current rule, effective on January 1, 2009, is compared with the revised anti-markup rule that took effect on January 1, 2008. The 2008 rule applied to anatomic pathology and not to other services," said Hindmand. "So by that logic, it seems clear that CMS was not intending to exclude anatomic pathology as it asked for comments this fall as part of the process of revising the anti-markup rule. Revisions that resulted from this process were incorporated into the anti-markup rule which became effective on January 1, 2009."

Wood explained that, by itself, the anti-markup rule is relatively clear. What raises these questions is the commentary that CMS includes when it issues a rule. "The commentary for this anti-markup rule implies that anatomic pathology services are covered," she said. "But there is arguably no supervision requirement under Medicare for histology processing because CLIA doesn't cover histology processing. Thus, if Medicare doesn't have a supervision requirement, that raises the question that maybe the anti-markup provision doesn't apply.

"Although this position is not clearly outlined in the regulation, it's contained in the commentary," she added. "The commentary does not carry the same weight as the regulation. But the commentary influences how the government interprets the regulation itself. The regulation itself could be read that way or not. In fact, you could argue both sides of the issue.

"So, the fact that you can argue both sides lends credence to the argument that maybe the anti-markup rule doesn't apply to histology processing," Wood said. "But that doesn't appear to be the government's intent.

"During the comment period before the new anti-markup rules became effective, some experts requested that CMS require CLIA-level supervision for all anatomic pathology tests," stated Hindmand. "But CMS rejected that idea. CMS said it was not changing the supervision standard. It stated that the supervision standard is whatever is contained in the Medicare rules. However, no supervision requirement can be found in the Medicare rules for histology processing.

Easier To Understand

"In making these revisions last fall to the proposed regulations in the 2009 Medicare Physician Fee Schedule, CMS said it was attempting to simplify the rules," Hindmand said. "As published in the *Federal Register* on November 19, 2008, these proposed regulations revised the Medicare anti-markup rules applicable to all professional and technical component diagnostic services.

"In general, CMS did succeed in making the rules easier to understand," he commented, "particularly for ordering group practices that provide and bill for the technical component of diagnostic testing services, including anatomic pathology. The rules provide two alternative tests that pathologists would apply to determine if the anti-markup rule applies." TDR

Contact Jane Pine Wood at 508-385-5227 or jwood@mcdonaldhopkins.com; Rick L. Hindmand at 312-642-2203 or rhindmand@mcdonaldhopkins.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last week, THE DARK REPORT was in Birmingham, England, to participate in the sixth annual *Frontiers in Laboratory Medicine* (FiLM) conference. This event is co-produced by the **Association of Clinical Biochemistry** (ACB) and THE DARK REPORT. It provides an opportunity to learn more about healthcare in the United Kingdom and how clinical laboratories serve this single-payer health system. As most readers in the United States know, the **National Health Service** (NHS) of the United Kingdom is often held up as an example of a universal coverage health system that might inspire a similar universal health program in this country.

MORE ON: UK's NHS

What follows is a sampling of three items which appeared in one day's newspaper coverage. They show that the UK's National Health Service does have its share of problems. In the January 27, 2009, issue of the *Daily Mail*, a national newspaper in England, the first health story discussed the latest delays in implementing the NHS' ambitious £12 billion (US$17.2 billion) project to implement a single national electronic medical record (EMR) system. The project, launched in 2002, will link 30,000 general practitioners with 300 hospitals. Originally scheduled to be completed by 2010, the news was of another pushback in implementation. It will now likely be later than the current target of 2015. This IT challenge is mirrored in the United States, as the **Veterans Administration** (VA) has similarly overshot its national EMR implementation timetable.

NHS BRANDED AS "AGEIST" BY CRITICS

Another healthcare news story in the *Daily Mail* carried the headline "The NHS is ageist, say half of doctors." A survey of 201 doctors in the **British Geriatrics Society** (BGS) determined that 47% thought that the NHS was ageist—meaning that elderly people were less likely to have their symptoms diagnosed and treated. A recent report in the *British Medical Journal* indicated that only 62% of people aged 50 or older in England get the care recommended for their condition. Legislation or new regulations may address the issue of age discrimination in health and social care.

ADD TO: Food Search

This odd news story in the *Daily Mail* reported that six councils were participating in a pilot program that would pay inspectors $12.20 per hour to visit people in their homes and offer advice on what people were eating and the food they were throwing away. By year's end, it is expected that 8,000 of these inspectors will be out visiting residents in the UK and providing dietary advice!

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how both employers and health insurers are offering wellness plans. This gives laboratories a new opportunity to provide added value lab testing services.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, February 23, 2009.