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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

## Med Techs Who Add Value to Patient Care

IT IS ALWAYS INSPIRING TO LEARN THE STORIES OF CLINICAL LABORATORY SCIENTISTS who spot opportunities to improve patient care, then take initiative to seize that opportunity and help patients get better. Such is the case of a medical technologist in a 25-bed rural hospital who now participates in daily rounds.

Christina L. Bard, CLS(ASCP), MBA, is the laboratory manager at **Putnam County Hospital** in Greencastle, Ind. Her hospital has a pathologist onsite only one day per week. Seizing the opportunity to become part of the team that makes daily rounding earlier this year, she recognized that her expertise and knowledge of laboratory medicine, when brought to the patient's bedside, could make a difference.

That is the genesis of the story we report on pages 10-12. It is an example of how any clinical laboratory scientist, clinical chemist, or pathologist can add value in the patient care continuum by leaving the four walls of the lab and engaging with physicians, nurses, and other clinicians as they conduct daily rounds within the hospital.

Bard shared with us multiple examples of how, at the bedside of different patients, she recognized that existing lab test data for these individual patients could signify other conditions or therapeutic opportunities than the ones under discussion by the rounding team. In calling attention to how these test results could be interpreted in a different context, her observations would sometimes trigger a reassessment by the care team. In turn, the team would act on that information in ways that produced a more accurate diagnosis, followed by effective therapies that helped the patient recover faster.

Clinical laboratory scientists and medical technologists are the bedrock of laboratory medicine in the United States. Bard's initiative to get out of the lab and interact daily with clinicians at the bedside should inspire others to do the same within their hospitals, health systems, physicians offices—wherever they work. This is important for another reason: healthcare's shift from volume to value. As labs get paid less for the tests they perform, they should leverage their knowledge to be paid more for the value they can contribute when they collaborate with clinicians in ways that directly improve patient outcomes while lowering the overall cost of care. TDR

# HDL Founders, BlueWave Sued for $600 Million

## Trustee also has collection agency dunning physicians who accepted inducements from HDL

***CEO SUMMARY: Unlike federal prosecutors, who to date have shown little interest in seeking to recover money from either the physicians who accepted inducements from Health Diagnostic Laboratory or many of the shareholders, executives, and sales consultants of HDL, the trustee of the HDL bankruptcy is moving aggressively to attempt to collect money from all of these individuals. Just 10 days ago, the trustee filed a $600 million lawsuit that lists 76 counts against more than 100 defendants.***

LEAVE IT TO THE PRIVATE SECTOR to police the clinical laboratory business in a way that federal prosecutors have failed to do. Creditors in the bankruptcy of **Health Diagnostic Laboratory** of Richmond, Va., just sued the company founders and their sales consultants for $600 million!

And that's just part of the story about aggressive efforts by HDL's creditors to recover hundred of millions of dollars from those associated with the troubled lab company. Over the past month, the law firm that represented HDL during its start-up and operating years agreed to a $20 million settlement with HDL's creditors.

Also during the past month, it was learned that the HDL creditors engaged a law firm that is now working to collect money from physicians who accepted alleged kickbacks and other forms of illegal remuneration from HDL in exchange for referring patients to HDL for medically unnecessary or inappropriate lab tests.

Both of these actions may not have a precedent in the bankruptcy of a clinical laboratory company. But they indicate that lawyers, accountants, and client physicians who are willing to participate in schemes with a lab company that possibly violate federal and state laws now have a new source of risk and exposure, independent of the risk of criminal and civil actions by federal and state prosecutors.

Now, on top of these aggressive collection actions comes the latest chapter in the troubled HDL saga. In a 205-page lawsuit filed Sept. 16 in the U.S. Bankruptcy Court for the Eastern District of Virginia (Richmond Division), Richard Arrowsmith,



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

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trustee of the **HDL Liquidating Trust**, lists 76 counts against more than 100 defendants. Those defendants include HDL founders Tonya Mallory, Joseph McConnell, and Russel Warnick; its former sales contractor **BlueWave Healthcare Consultants**; and BlueWave executives Robert Bradford Johnson and Floyd Calhoun Dent.

## 'Improper Practices'

The 76 counts include conspiracy; fraud and intentional interference with contracts; breaches of fiduciary duty; and fraudulent transfers, according to reporting by Katie Demeria in the *Richmond Times Dispatch*. "The allegations focus on alleged kickbacks paid to physicians to induce them to use HDL's services and in the process order medically unnecessary blood tests," she wrote. *(See TDR, Sept. 14, 2015.)*

The lawsuit seeks to recover the more than $600 million in losses that the creditors suffered, court documents show.

From the founding of HDL in 2008, the lawsuit said HDL's founders conspired with BlueWave to sell HDL's tests through improper and illegal business practices. Mallory, Warnick, McConnell, Dent, and Johnson, "collectively hatched a scheme to build and grow HDL through illegal and fraudulent business practices and to share the spoils with BlueWave, all for their personal gain," the lawsuit said.

## Payments To BlueWave

Among the more than 100 defendants are what the lawsuit called BlueWave Transferee Defendants who got tens of thousands of dollars to millions of dollars in transfer payments from HDL to BlueWave and then to the transferee defendants.

"The additional defendants include dozens of entities created to transfer payments from HDL to BlueWave, along with dozens of independent sales contractors hired by BlueWave to sell HDL blood tests," Demeria wrote.

"Each of the BlueWave Transferee Defendants was actively engaged in the heavily-regulated healthcare industry, knew or should have known that the business practices they carried out as described herein were illegal and improper, but engaged in such business practices because they received financial benefits from them, including through transfers as a result of the BlueWave Agreement," the court documents showed.

Companies operated by Dent, Johnson, and Jeffrey Cornwell were named as Major Sales Contractor Defendants who gave healthcare practitioners (HCPs), "gifts such as sporting event tickets, gift cards, electronics, and other items to induce HCPs to order tests from HDL, a violation of federal and state anti-kickback laws."

## Misrepresentations To Payers

In addition, the major sales contractor defendants misrepresented facts to such insurers as **Cigna Health and Life Insurance Company**, **Connecticut General Life Insurance Company**, **Aetna**, and other private insurers about the true nature of those business practices, the court documents showed.

"The major sales contractor defendants falsely represented, among other things, that the amounts charged for the tests included a co-pay, co-insurance, or deductible amount that HDL intended to collect from patients (when HDL routinely did not collect such amounts), that HDL's business and the sales of HDL tests by the Major Sales Contractor Defendants were conducted in accordance with the Anti-kickback Statute and other healthcare laws (when in fact they were not), and that the HDL tests that the Major Sales Contractor Defendants sold were medically necessary (when many times they were not)," the lawsuit said.

The major sales contractor defendants also regularly told HCPs that HDL did not intend to collect from patients for co-

## Tipton Golias, Owner of Helena Laboratories Named in HDL Lawsuit as Largest Shareholder

**ONE ELEMENT** in the Health Diagnostic Laboratory case that has gone largely unreported is the name of the largest HDL shareholder.

Court documents filed in the HDL bankruptcy case this month showed that Tipton Golias was HDL's largest stockholder and that he invested equity amounts in HDL that were mischaracterized as a loan. Golias is the founder, chairman, CEO, and director of **Helena Laboratories Corp.**, a company in Beaumont, Texas, that makes clinical laboratory instruments and reagents. Its clients are medical centers, hospitals, reference laboratories, and private doctors' laboratories. The lawsuit said Helena was an affiliate of HDL "at all relevant times."

Golias owned 38.4795% of HDL's stock and his son, defendant Joseph Golias, owned 5.21% of HDL's stock; defendant Donald Golias, another son of Tipton Golias, owned 2.605% of HDL's stock; defendant Karla Falgout, a daughter of Tipton Golias, owned 2.605% of HDL's stock, court documents showed.

Also Tipton Golias was the trustee of the Wyndell L. Golias Voting Trust, which owned 1.1164% of HDL's stock, the lawsuit stated. Taken together, the Golias family shareholders, including Tipton, Joseph, and Donald Golias, and Karla Falgout, and Tipton Golias as trustee of The Wyndell L. Golias Voting Trust, owned 50.02% of HDL's stock, the court documents showed.

pay, co-insurance, or deductible amounts, the lawsuit said. In addition, these defendants sold HDL tests to healthcare practioners (HCPs) by promoting the fact that the HCPs would receive process and handling fees as a result of shipping patients' specimens to HDL, court documents showed.

### Medically Unneeded Tests

These efforts induced HCPs to order medically unnecessary tests for patients, causing Cigna and Aetna to pay inflated and fraudulent claims to HDL.

The process and handling fees were thinly-veiled kickbacks that induced physicians to order medically unnecessary tests and violated state and federal anti-kickback laws, the lawsuit explained.

"According to HDL's bankruptcy estate, hundreds of millions of dollars are owed to HDL creditors because of those kickback practices. Creditors include the federal government, which is owed $94 million as part of the settlement, as well as private insurers including Aetna (owed $77 million), Cigna (owed $59 million) and **United Healthcare** (owed $96 million)," Demeria wrote.

In an unrelated development, the law firm of **LeClairRyan** agreed to a $20.4 million settlement with HDL's creditors. Last fall, HDL's trustee sent a letter to LeClairRyan outlining claims rooted in the legal services that LeClairRyan provided to HDL from 2008 until last year, Demeria reported. In that time, the **U.S. Department of Justice** began investigating allegations that HDL was providing kickbacks to physicians. The terms of the agreement are not an admission of guilt by LeClairRyan. LeClairRyan said, "As stated in the settlement, we do not believe LeClairRyan is responsible for the actions that led to the government investigation or bankruptcy of HDL."

The other news of significance involves the HDL creditors' use of law firm **Wolcott Rivers Gates** to send demand letters to physicians who accepted various forms of remuneration from HDL—such as fees for processing specimens. The letters request that these physicians return those payments. **TDR**

*—Joseph Burns*

## Legal Update

# Attorney Jane Pine Wood to Be Chief Legal Counsel at Bio-Reference

*Many pathology group clients caught by surprise, disappointed to lose access to her extensive experience*

One of the most widely-respected and trusted attorneys serving the clinical laboratory industry and anatomic pathology profession is leaving private practice to join the corporate world.

Effective October 1, 2016, Jane Pine Wood becomes the new Chief Legal Counsel and Compliance Officer for **Bio-Reference Laboratories, Inc.**, of Elmwood Park, New Jersey. Wood will leave **McDonald Hopkins**, based in Cleveland, Ohio, where she has practiced since 1988.

**Jane Pine Wood**
Attorney accepts position at Bio-Reference Laboratories.

In a statement to THE DARK REPORT, Wood said, "After almost three decades of the private practice of law, I have decided to go down a new path. This has been a difficult decision for me, and I remain very loyal to my firm (and to my colleague, Rick Cooper), but after 30 years, I'm ready to try my hand at something new, including an increased focus on my business and management skills!"

### Hundreds Of Path/Lab Clients

Lab and pathology clients of Wood have received letters from her law firm announcing her departure. The effect of this decision will be significant, because THE DARK REPORT believes that—just in the field of pathology and clinical laboratory medicine—the number of her clients is in multiple hundreds. Additionally, Wood was regularly a key legal adviser to pathology and laboratory associations and societies on the full range of issues involving federal and state legislation, the Medicare and Medicaid programs, CLIA, the FDA, and managed care contracting policies.

By joining Bio-Reference Labs at this time, Wood will be dealing with new and tough challenges. The nation's third-largest clinical lab company, BRLI was acquired last year by **OPKO Health, Inc.**, a pharmaceutical firm located in Miami.

OPKO Health sees opportunities to leverage BRLI's capabilities in managed care contracting for drugs moving through its pipeline. OPKO also has a prostate cancer test, the 4KScore, which is supported by strong clinical data. Bio-Reference Laboratories' sales force is beginning to market this proprietary test to physicians nationwide.

Jane Pine Wood will speak at a special webinar organized by THE DARK REPORT. It will take place on October 12 and she will be joined by attorney Richard S. Cooper, of McDonald Hopkins. Wood and Cooper will discuss 2017's key legal, regulatory, and managed care contracting issues. It is an opportunity for labs and pathology groups to benefit from Wood and Cooper's insights and recommendations. TDR

*Webinar details at: www.darkdaily.com.*

# First CAP 15189 Accreditation for a Children's Hospital Lab

## Lab leadership used ISO 15189 as challenge for the lab team to raise its already-high quality

***CEO SUMMARY: It's now official. St. Jude Children's Research Hospital is the first children's hospital to earn accreditation to ISO 15189 under the College of American Pathologists. What is more interesting, however, is how lab leadership used the quality management system of ISO 15189 to help lab staff to raise the quality of lab services. The motivation was the need to be ahead of such trends as declining lab budgets, higher standards of patient care, and less tolerance for errors by patients and payers.***

EARLIER THIS YEAR, the Department of Pathology at **St. Jude Children's Research Hospital** in Memphis was accredited to the ISO 15189 standard under the **College of American Pathologists** (CAP). St. Jude is the first—and so far only—children's hospital in the nation to achieve this accreditation.

Richard Warren, MHA, DLM(ASCP), the Administrative Director of the Department of Pathology, explained that the lab staff pursued the ISO 15189 accreditation in response to a challenge in 2012 from David Ellison, MD, PhD, who, at that time, had just recently been appointed department chairman.

"ISO inspectors were systematic and thorough in their approach, as you would expect," he noted. "But what we didn't expect was that the inspectors would not accept a superficial fix or a process modification that was not well thought out. This approach differs from some standard accreditation processes that may accept minimal demonstration of compliance.

"From my perspective and for our lab, the whole ISO 15189 accreditation process was not about meeting the ISO standard specifically," stated Warren. "Rather, it was about building a foundation of processes to support our quality management system and help our staff and management provide world-class laboratory services to our patients and other customers."

### Clinical Lab Staff

The St. Jude lab has a staff of 325 FTEs, about 200 of whom work in the clinical pathology division and 125 are in research. Also, the lab has 10 pathologists with subspecialties. It performs 800,000 billable tests each year and about 1.7 million reportable tests, said Warren.

"We already operated a high level, but Dr. Ellison felt that we still had opportunities to improve some of our infrastructure, our ability to communicate among our labs more effectively, and do more robust risk management," explained Warren. "Pursuing 15189 was the path we chose to raise our level of quality to the next level. Our ultimate goal is to become a world class laboratory.

"In terms of adapting to change, probably our biggest challenge involved adopting the ISO 15189 approach to risk

management," stated Warren. "It specifies a robust way to identify the steps we could take to prevent problems before they happen and to implement the subsequent corrective actions that follow when a problem is identified.

"This is an important reason why I recommend that lab managers be able to accept input into processes from all levels of stakeholders and be flexible in how they approach compliance with these standards," advised Warren. "Compliance cannot always be pushed down from the top. This is why we built consensus across our management team and lab staff."

The St. Jude lab team shared three lessons from its 15189 accreditation. "The first lesson was our realization that labs seeking accreditation to ISO 15189 should carefully proceed if the management staff are averse to change," commented Warren. "This is why we slowly pursued this accreditation.

"Lesson number two is that, even though our lab had a robust management system founded in its CLIA accreditation processes, some members of the leadership team still tended to operate independently," he explained. "They were unaccustomed to working in a different way that is consistent with a truly integrated quality management system. This relates to the first lesson that management must be ready to accept the changes inherent with ISO 15189.

## Becoming Team Players

"More specifically, autonomous managers needed to become team players," continued Warren. "Before being accredited to ISO 15189, the medical directors and the managers of each laboratory section had much autonomy in how they approached solving problems, structuring areas of compliance, or conducting validations.

"As soon as we implemented quality oversight, our directors and managers had to get used to the idea that they were subject to a higher level of scrutiny and accountability within their operations," added Warren. "It was a big change for everyone to have a greater level of involvement in quality management within their lab sections. This quality oversight has tremendously benefited our operations by providing an 'outsiders' viewpoint.'

"Third was the recognition by our clinical laboratory's managers and staff that ISO 15189 standards directly resulted in improved processes," added Julie McGowan, MA, DLM(ASCP), CMQ/OE (ASQ), Quality Program Manager for the Department of Pathology. McGowan was hired in 2012 to head up the accreditation project. "This was particularly true for processes used by the lab staff to identify and solve problems."

## Finding Problems Earlier

Improved processes meant that use of ISO 15189 made it easier to identify problems earlier. "As one example, there was a new manager on the second shift where all but one or two of the staff on that shift were new employees too," recalled McGowan. "The new manager reported that the staff was making a lot of mistakes typical of newly-hired staff.

"That told me there was something wrong with our processes," McGowan commented. "After we evaluated our processes as a group, we decided to review our training program. If all members of the staff were making the same mistakes, that showed we needed to revise our training process. Once we did that, we fixed the problem."

"Our leadership team was adaptive to change, but we grossly underestimated the level of detail and precision required to address some of the management and technical standards within 15189," concluded Warren. "Compared to our existing rigorous quality management, ISO 15189 required us to be more specific, thorough, and precise in all of our documents and management processes." TDR

*—Joseph Burns*

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Regulatory Update

# Brooklyn Tox Lab Suspended for 30 Days by NY Dept. of Health

In Brooklyn, N.Y., a toxicology laboratory has been shut down temporarily since Sept. 9 by order of the **New York State Department of Health**. The lab was cited for failing to perform calibration and quality control procedures properly,

The lab company is **Advanced Clinical Laboratory Solutions Inc.**, which describes itself as, "a physician driven, patient minded, client-focused clinical toxicology-testing laboratory."

In an email response to a query from The Dark Report, the DOH said, "On Sept. 9, 2016, the department issued an administrative order suspending Advance Clinical Laboratory Solutions, Inc.'s (ACLS) clinical laboratory permit in the category of clinical toxicology for 30 days. As set forth in the order, the suspension was deemed necessary after department inspectors found serious deficiencies at ACLS' clinical toxicology laboratory, which could potentially result in the laboratory's reporting of invalid test results."

In the email, the department said, "Deficiencies include: using unlicensed personnel to perform testing; failing to properly perform calibration and quality control procedures; and following technical procedures that are not in accordance with the laboratory's own guidelines and/or New York State and federal requirements."

The department could take additional enforcement action, including revocation or suspension of its license, DOH said.

"The department continues to review information from the laboratory to determine the potential impact, if any, the above described deficiencies may have had on previously reported test results," the email said.

In response to an inquiry by The Dark Report, ACLS CEO Leon Reyfman, MD, FIPP, RpH, sent the following statement: "ACLS is committed to providing quality laboratory services and we are proud of the services we provide to the healthcare community. We continue to work with the NYSDOH to improve and ensure our ongoing quality. ACLS continues to provide toxicology services by utilizing a national reference laboratory. ACLS also continues to provide molecular genetic testing."

## Anesthesiologist Is Director

Reyfman is an anesthesiologist and a pain medicine specialist at **Mount Sinai Beth Israel** in New York City. He is also the director, Interventional Pain Management, for **Pain Physicians NY**. In his LinkedIn profile, Reyfman said he is board-certified through the American Board of Anesthesiology in both anesthesiology and pain management.

On its website, ACLS says it is a CLIA-certified lab and licensed to perform testing in all of the United States. For New York State, it is a DOH-accredited clinical laboratory for molecular genetic testing. It also meets the standards for Secure Laboratory Information Systems (LIS), Code of Federal Regulations (CFR) 21 compliant, and is Health Insurance Portability and Accountability Act (HIPAA) compliant, it says.

*—Joseph Burns*

Adding Value

# Meet the Med Tech Who Does Daily Rounds in the Hospital

*Participating on patient rounds each morning allows lab team to contribute to better patient care*

TO MAKE THE TRANSITION FROM VOLUME TO VALUE, pathologists and clinical laboratory scientists are beginning to leave the four walls of their labs to engage clinicians in ways that add value to the lab tests performed on their patients.

That's exactly what one medical technologist is doing in a community hospital in the Midwest. Daily, she leaves the lab and makes rounds with the hospital staff.

This is a twist on the oft-stated fact that pathologists are the "doctor's doctor." It is more common for pathologists to consult with physicians in the selection of the most appropriate lab tests, then help with interpreting the lab results to identify the best therapies for those patients.

## Med Tech Joined Rounds

In April, this med tech joined the daily rounds at **Putnam County Hospital**. Christina L. Bard, CLS (ASCP), MBA, the Laboratory Manager at the hospital, is part of the team making rounds that includes physicians, nursing leadership, and other clinicians, at the 25-bed critical access hospital in rural Greencastle, Ind. The laboratory has a staff of 18 who run about 150,000 billable tests each year.

Despite its size, the clinical lab plays a vitally important role in improving patient care. This comes, first, as a direct result of having Bard and other lab leaders participate on patient rounds and, second, because the lab team facilitates communication among all hospital staff.

Like many of the nation's critical access facilities, Putnam County Hospital is too small to have a full-time pathologist on staff. "We have a pathologist who comes here for eight hours a week," Bard explained. "It means the physician's physician is not on-site every day. That is why it made sense for the lab leadership team to go on the daily rounds. Typically rounds start at 10:30 am in the ICU.

## Improving Patient Care

"This spring, the hospital engaged nursing leadership in a program that involves patient rounding every day," she said. "The lab answers through the organization to the chief nursing officer. One day we got a note from her that requested participation by the nurse managers.

"When she sent this email encouraging her nurse managers to participate, I thought, 'I'm also going on rounds because I'm part of the patient care team!'" stated Bard. At that point, she realized the importance of having a professional from the clinical laboratory among those rounding with physicians.

"After the first day, I told the nursing manager that I was the only member of the team who was not a nurse or therapist. I asked if she had a problem with that," Bard said. "'Not at all,' she told me. 'Sometimes we have lab questions and so it's good to have you there.'

"As a result, my participation created a huge opportunity for us in the lab to build

## Laboratory Manager Offers Advice Based On Her Experience Doing Daily Rounds with Clinical Team

**WHEN ANOTHER MEMBER OF THE** laboratory staff needs to do rounds, Laboratory Manager Christina L. Bard, CLS (ASCP), MBA, has prepared the following suggestions.

### Things to DO During Rounding

- Print (or access) patient census review admitting diagnosis and current working diagnosis.
- Review patient results prior to rounding.
- Review critical results – was a repeat test ordered after treatment interventions?
- Example of critical alcohol: was a repeat value after time/therapy performed?
- Compare diagnosis against lab tests ordered to ensure they are appropriate.
- Example of chest pain diagnosis: was a Troponin ordered x3 Q 6?
- Review the last two times a laboratory test was performed to look for changes in the patient's status.
- Example: Yesterday and today's H&H results: was there a change? If so, was the patient transfused, taken to surgery, etc.?
- For patients with an infection, review any culture results for the entire visit, not just the last 24 hours.
- Compare culture susceptibilities against antibiotics given or, if a pharmacist is on the rounding team, take the report for him/her to review.

### Things to AVOID During Rounding

- Do not go to rounds unprepared. Be ready to answer questions about the patient's lab results, including how and when a lab specimen was collected and what the results may mean in a particular situation.
- Do not arrive late.
- Avoid unnecessary, non-clinical comments about a patient or patient's family. Be respectful as you do not know who is listening and who might be related to the patient.

relationships that we might not have otherwise and to partner with those on the patient care teams," she noted. "In fact, we've brought much value. The care of specific patients has changed based on the information we bring during rounds.

### Fostering Communication

"Three examples paint the picture of our role," Bard commented. "In the first week, the physician and nurses were looking at a particular patient's lab results and talking about how the patient had shortness of breath. During the discussion, it became apparent that there were other values that are relevant to the patient's treatment. I spoke up to say that the patient's blood work showed her mean corpuscular volume was over 100, which means she had macrocytic anemia. She didn't need iron; she needed vitamin B and folic acid.

"Following that episode, our ICU nurse manager contacted me in the following week to say she was planning her monthly staff meeting and asked if someone from the lab could do a 15-minute educational session on anemia," explained Bard. "As a result of that one meeting, I am on the nursing agenda for their monthly meetings to present relevant lab topics that help the nurses take better care of their patients.

"At that first session with the nursing staff, I explained why a patient with low hemoglobin doesn't necessarily need a transfusion. Nor does it mean the patient needs iron," she said. "I explained which lab tests are appropriate in this situation. It was a short presentation of 15 or so slides, which I left behind for them as a handout.

"Here's example number two," continued Bard. "Transitions of care are a

challenge in every healthcare facility. A urinalysis was done for an ER patient. Based on those results, it was determined that the patient needed a urine culture. The patient has several other health issues and concerns. Because of all those problems, she was admitted to the ICU.

"Two days later, when the urine culture came back, the result was positive for an infection and I saw what the organism was," recalled Bard. "During rounds the next day, they were discussing how the patient's glucose was still high and she was still out of it. They were still treating the diabetes.

"I happened to have the urine culture results with me, and when I showed them to the physician that day, he prescribed an antibiotic," she said. "This is a good example of where the lab intervened to improve patient care.

"The fact that the patient had an infection was easy to miss," she added. "Thus, having someone from the lab at the rounding huddle during the discussion helped that patient get the care she needed.

"Here's the third example. For inpatients, a set of labs gets ordered every day," observed Bard. "One afternoon, a newly-admitted patient had a full CBC done. For that patient, the test generated results for hemoglobin, hematocrit, the white blood count, and the red blood count. At 6 pm on that patient's first night, all of those levels were slightly decreased but not enough that the patient needed a transfusion.

## Need for Transfusion?

"The next morning, the patient's hemoglobin had dropped two full grams, which is a significant decline," recalled Bard. "She had gone from about a nine or 10 down to seven or eight. The nurse and the doctor reviewing the results were alarmed and thought they needed to transfuse."

During the discussion, the patient's fluids were reviewed. Because the fluids were running at a high rate, it was suggested that this could be affecting the lab values.

"Hearing that, I suggested that we should turn the IV off," Bard added. "I also suggested we do a re-collect, and then recheck the results. It turned out that the patient did not need a transfusion at all.

"Having such successes during daily rounds has led to better interactions between the lab and members of the direct patient care team members," she stated. "This has been noticed by many people in the hospital. We now have one physician who calls the lab to ask us about which tests he should order for certain patients.

"What is noteworthy in our experience is that we achieved this success after spending only about 30 minutes per day on the actual rounding," offered Bard. "There is some preparation that's required before rounds begin.

"First thing every morning, I print a census and pull up each patients' results," she said. "I quickly review them before the rounds begin. In total, it takes probably 45 minutes to an hour for both the pre-rounds review and participation in each day's patient rounding.

"Our lab has always been responsive to physicians' needs and I don't think we're any more responsive now that we are a part of the rounding team," Bard added. "Having a laboratorian at rounding is a resource for care providers to ask questions about results or what appropriate test to order. In return, this provides our patients with the best possible care.

"The big difference since the lab leaders joined daily rounding is that there is much greater awareness among physicians and nurses about the vast knowledge our lab has that relates to direct patient care," concluded Bard. "Participation in daily rounding demonstrates the extra value that the laboratory team provides when we partner with our clinical colleagues." TDR

*—Joseph Burns*

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# Ob-Gyns Dispute Need For Genetic Test Counseling

## Requiring counseling and preauthorization has negative effect on patient care, they add

***CEO SUMMARY: Obstetricians and gynecologists have told health insurers that requiring genetic counseling before approval of genetic testing has a negative effect on patient care and is unnecessary. Recently, two ob-gyn associations went on record opposing such requirements. Ob-gyns say they are trained and capable to recognize which patients need such testing. Clinical labs offering genetic testing have an opportunity to serve ob-gyns by assisting them in getting approval for these genetic tests.***

INTERESTING BATTLE LINES ARE BEING FORMED between physicians who order genetic tests and health insurers that require genetic testing before these tests can be ordered.

Just seven months ago, the **American College of Obstetricians and Gynecologists** and the **American Congress of Obstetricians and Gynecologists** joined those battle lines. The two national medical associations complained that health insurers' efforts to restrict access to genetic testing have a negative effect on patient care.

These physicians point out that more insurers now stipulate burdensome prior authorization for physicians seeking to order genetic tests. One of the requirements is that only genetic counselors can provide such counseling to patients.

"ACOG opposes such attempts to restrict the scope of practice of obstetrician-gynecologists, who are fully qualified to provide pre-test counseling to their patients," the ob-gyn organizations said in a statement issued in December 2015. "Board-certified ob-gyns are skilled, dedicated healthcare professionals with more-than-sufficient training to order genetic testing and to counsel patients prior to and after testing. In many cases, a woman's trusted ob-gyn is the ideal and preferred messenger of health information."

In some areas of the country where there are fewer genetic counselors, requiring women to get genetic counseling only from genetic counselors will hurt patients particularly hard, ACOG said.

Since the statements were issued, insurers have done nothing to change their requirements, stated Mark DeFrancesco, MD, an ob-gyn in Waterbury, Conn., and ACOG's immediate past president.

### An Opportunity for Labs

This issue is important for clinical laboratories because, as DeFrancesco explained, some labs work closely with physicians to ensure that insurers approve physicians' requests for such testing.

"Some insurance companies do not require genetic counseling, but many do have such requirements and almost all insurers require preauthorization," he

said. "That's where it's important for us as physicians to work closely with labs that do this testing.

"One example of this collaboration involves a major lab," noted DeFrancesco. "It asks me to fill out the paperwork, indicate the family history and the other demographic data and send that information with the specimen to the lab. Then, the lab runs interference for me with the insurance company.

## Labs, Physicians Collaborate

"The lab will call the insurance company, present the case to them, and generally get authorization," he stated, "I don't have an exact count, but it's been very rare that any insurer has turned down one of my patients when I send test requests to this lab.

"That tells you that my selection process for deciding when it is appropriate to order a genetic test must be okay," added DeFrancesco, "After all, when the insurance companies review the information I submit, they agree with me that the patient meets the criteria. I'm not saying that I'm so special. I'm a typical ob-gyn who knows how to take a family history and knows how to apply that information when genetic testing would be appropriate.

"My point is that when physicians do what they're trained to do, then usually patients get the testing they should get," he emphasized. "That raises the question: Why do health insurers put restrictions in place and make it more difficult for patients to get the genetic tests that are appropriate for their care?

"As physicians, we order these tests based on whether a patient meets certain criteria," he explained. "Regardless of their specialty, in medical school physicians learn that taking the family history is critical. That's why it's one of the first things considered when ordering tests for patients.

"Of course genetic testing is getting more complex," noted DeFrancesco. "But the fact remains that the family history tells what you need to know about that patient's risk. Are there more than 'x' number of members of the family who have had breast cancer, ovarian cancer, uterine cancer, pancreatic cancer, or colon cancer?

"There are certain algorithms that physicians have been trained to use to make the fundamental decision of whether the patient reaches a certain level of suspicion and that suspicion is strong enough to qualify for genetic testing," he added.

"The critical part where a genetic counselor is needed is to interpret results when they are positive," he explained. "When the genetic test results are negative, the critically important issue to explain to the patient is that—while the tests are negative—that fact does not mean that this patient will never get cancer.

"In simplest terms, it means the patient is not in the high-risk category," continued DeFrancesco. "That patient remains at a normal risk for cancer. So this doesn't absolve the physician of going for mammograms in the future. But a genetic counselor is not needed to give patients that message.

"Genetic counselors certainly have a role, especially when a result is positive," asserted DeFrancesco. "Then the counselor needs to explain the result and discuss what that result means for that individual patient based on the patient's family and other genetic characteristics.

## Patient Access to Tests

"But for insurers to restrict access to gentic testing unless a genetic counselor is involved does limit access to this testing," DeFrancesco added. "In fact, many insurance companies allow us to order genetic tests and do the genetic counseling, and some companies have their own genetic counselors, which is fine. But the few health insurers that don't allow us to do the counseling are delaying care for these patients," he said. TDR

*—Joseph Burns*

*Contact Mark DeFrancesco, MD, at 203-574-5501.*

IVD Update

# Cepheid, Sequenom Acquisitions Further Consolidate Lab Testing

*Danaher purchases Cepheid for $4 billion while LabCorp snaps up Sequenom for $371 million*

TWO ACQUISITIONS FURTHER consolidated the clinical laboratory testing industry in recent weeks. The acquired companies were **Sequenom** and **Cepheid**.

Sequenom went first. On July 27, **Laboratory Corporation of America** announced an agreement to acquire Sequenom for a purchase price of about $371 million.

It was Cepheid's turn next. Just 11 days later, on Sept. 6, **Danaher Corporation** disclosed an agreement calling for it to pay approximately $4 billion to buy Cepheid.

San Diego-based Sequenom had revenue of $120 million in 2015. It offers proprietary tests in the women's health and oncology markets. Founded in 1994, the company has struggled financially in recent years. It says it expects about 170,000 accessions for non-invasive prenatal testing (NIPT) in 2016.

## LabCorp Shifts Its Test Mix

For LabCorp, the acquisition of Sequenom adds higher-cost proprietary assays to its test mix. Both of the two national laboratory companies are working to increase the proportion of reference, specialty, and esoteric tests they perform. This is important because of the expected multi-year price cuts that the federal **Centers for Medicare & Medical Service**s is expected to implement to the high-volume, automated tests on the Medicare Part B clinical laboratory fee schedule beginning in 2018.

Cepheid is a different company than Sequenom in the respect that it manufactures and sells molecular testing systems to clinical laboratories and research programs. It is profitable and has grown at a steady pace in recent years, in the range of 8% to 9% per year. Based in Sunnyvale, Calif., Cepheid posted revenue of $538 million in 2015. The company is on track to increase annual revenue to $618 million this year.

## Danaher Builds IVD Portfolio

By acquiring Cepheid, Danaher adds to its existing portfolio of *in vitro* diagnostic (IVD) companies. It already owns **Beckman Coulter Corporation**, **AC Sciex**, **Radiometer**, **HemoCue,** and **Leica Microsystems**. Danaher now ranks as the world's fourth largest IVD company, with approximately $5 billion in annual revenue from its IVD businesses.

Another reason Danaher may have been interested in Cepheid is its product line for point-of-care and near-patient infectious disease testing. Hospitals are putting more effort into managing hospital-acquired infections and using lab testing to support better utilization and stewardship of antibiotics.

Both acquisitions continue the trend of consolidation, which means the largest companies continue to get bigger. TDR

# Patient Safety Expert Says: 'Tell Patients About Errors'

## ➤Additional developments in civil lawsuit filed about pathology error at university med center

***➤➤CEO SUMMARY: As described in a civil lawsuit filed by a whistleblower pathologist in Kansas in July, a chair of pathology allegedly misdiagnosed cancer and the patient's healthy pancreas was surgically removed. Court documents say that the pathologist then altered records to cover up the mistake and, when informed of this situation, the hospital did not conduct a formal investigation. However, recently, the patient, asking to remain anonymous, said he/she was now aware of the pathology error and alleged cover-up.***

THERE ARE NEW DEVELOPMENTS in the civil court case in Kansas City that alleges an incident where a chair of pathology altered a cancer report after a patient's essential organ was surgically removed and found to be normal.

The first development is that a lawsuit filed in this case has been withdrawn by the plaintiff, in part, because the patient involved has issued a statement reproduced in the court filing that he/she is aware of the alleged misdiagnosis and coverup by the hospital. Second, a national patient safety expert has spoken out about the issues involved when a medical error occurs and the providers fail to be honest with the patient.

As described in the July 25, 2016 issue of THE DARK REPORT, Lowell Tilzer, MD, a staff pathologist and former department chair in the Pathology Department at the **Kansas University Hospital**, alleged on July 1 that the current chair of the department had misdiagnosed a patient's tissue sample as cancerous. The result of the alleged misdiagnosis was allegedly incorrect surgery to remove a vital body organ or part of an organ, Tilzer said in a petition for legal review in the civil division of the District Court of Wyandotte County, Kan.

The petition did not name the department chair, but the current chair is Meenakshi Singh, MD, the Russell J. Eilers, MD, Endowed Chair and Professor of Pathology of KUMC's/KU Hospital's Department of Pathology. The surgery was done in August 2015.

### ➤Alleged Misdiagnosis

In court papers, Tilzer also charged that hospital administrators covered up the alleged misdiagnosis and changed the electronic hospital record as part of the cover up. He also sent a letter about the incident to **The Joint Commission**.

Court documents said that, after sending the letter to the Joint Commission, Tilzer was reprimanded in a meeting by the hospital CEO Bob Page and said he feared he would lose his job.

"The patient was not told of the misdiagnosis, and was not informed that the essential body organ was not cancerous," the petition for judicial review says. "For months KUMC/Hospital withheld the

# Court Records in Kansas Allege Falsified Electronic Health Record Used to Cover Up Pathologist's Error

**TWO INTERESTING DEVELOPMENTS** happened recently in the lawsuit that alleges a pathologist and a university medical center covered up an alleged medical error by the chair of pathology that led to the alleged removal of a healthy pancreas in a patient. The patient was told only that he/she was free of cancer following the surgery.

With little explanation, the whistleblower, Lowell Tilzer, MD, who is a staff pathologist and former head of the Pathology Department at Kansas University Hospital, asked that the court toss out his legal filing in the case. In the initial filing on July 1, Tilzer alleged that a misdiagnosis led to an incorrect surgery to remove a vital body organ or part of an organ. In his second filing made on July 29, Tilzer explained that the patient who was allegedly harmed by the error has come forward but asked to remain anonymous.

Tilzer requested that the court dismiss the case without prejudice because the hospital did not file an answer or motion for summary judgment. "Petitioner (Tilzer) believes further litigation of this claim is not necessary to protect him from retaliation at this time," the most recent filing said.

Tilzer's second filing also stated that, based on a statement from the unnamed patient, he believes the public interest will be protected adequately if the suit is dismissed. In his second filing, Tilzer included this statement from the patient:

*"In September of 2015 I had surgery at Kansas University Hospital. I believe I am the anonymous patient referred to in the lawsuit filed by Dr. Lowell Tilzer against Kansas University Hospital. I did not know about the lawsuit until Tuesday, July 26, 2016, when my surgeon at KU called me and asked me to sign an affidavit about my surgery. The affidavit exonerated the hospital from any responsibility for the actions alleged in Dr. Tilzer's lawsuit.*

*I was concerned about why I was being asked to sign the affidavit, and my subsequent research uncovered the existence of the lawsuit. I do not know who wrote the affidavit, but I did not give the hospital permission to share my medical information with the person who wrote the affidavit. I have no direct knowledge of the actions of the physicians alleged in the lawsuit, but I will not sign the affidavit and I am exploring my options regarding the circumstances of my diagnosis and surgery.*

*But for Dr. Tilzer's filing of the lawsuit, and my receipt of the affidavit, I would never have known of the possibility that my surgery may have been [medically] unnecessary. I appreciate Dr. Tilzer's concern for me and I wish him the best. I want to remain anonymous, but you may use this statement as long as my name is not disclosed."*

correct diagnosis from the patient, and, to the best of Tilzer's knowledge and belief, the patient is still unaware that the patient did not have cancer."

The next development in this case happened on July 29. In a second court filing, Tilzer asked that the court dismiss the case without prejudice because the hospital did not file an answer or motion for summary judgment. "Petitioner (Tilzer) believes further litigation of this claim is not necessary to protect him from retaliation at this time," the most recent filing said.

Included in Tilzer's latest court filing is a statement released by the patient, who chose to remain anonymous. The patient's statement is reproduced on the sidebar on this page.

According to Lisa McGiffert, the Campaign Director of **Consumer**

**Union's** Safe Patient Project, there are several disturbing issues in this case of medical error, based on the court documents and published news accounts. "There is an arrogance in the medical provider community that they know best when the patient should and shouldn't know about errors," observed McGiffert, during an interview with THE DARK REPORT.

"Who knows what's going to happen to that patient later because that patient might have adverse effects from that surgery?" she asked. Consumers Union is the policy arm of *Consumer Reports*.

For McGiffert, the patient has an absolute right to know about the alleged error. "It's ethical and very important for that patient to know about the misdiagnosis," she said. "Or, if the tissues were tested and not cancerous, and the tissues were removed, then the patient has a right to know that.

## Hospital Cover-Up Alleged

The fact that Tilzer alleges a cover up is a serious problem, McGiffert added. "Typically if a patient knows there was a misdiagnosis or some kind of error that's caused harm, then that patient would have to find a lawyer to take the case," she said. "So the burden is totally on the patient.

"This is a fundamental issue for patient safety advocates, like myself," continued McGiffert. "Unfortunately this probably happens in every hospital every day. Everybody knows but the patient. And when patients are in the dark, what happens on their next visit to the doctor? How does that patient know what to say?

"Physicians and other healthcare providers make decisions about whether the patient should know about the medical error and those decisions are based on what the physicians or providers think the patient needs to know," she said. "In other words, they take away that right from the patient.

"In this case, the patient was told that he or she is cancer-free and is probably happy about that," added McGiffert. "So physicians or other providers could believe that, if the patient is happy, then why give that patient bad news.

"But the patient also allegedly has no pancreas or at least part of the pancreas is gone," she said. "So, as stated in the court documents, that patient had surgery for a cancer that he/she did not have. Therefore, this patient has the right to know about this medical error.

## Conflict Of Interest For Docs

"The reason physicians don't want to tell patients in such cases is that they have a conflict of interest and they're taking the position that they have to protect themselves from lawsuits," McGiffert explained. There are quite a number of hospitals that are in the United States and probably in other countries that are wrestling with the issue of how to talk to patients when a medical error has occurred, she noted.

Following the dismissal of Tilzer's lawsuit, KUMC/Hospital released a statement. As reported by public radio station **KCUR**, the statement said, in part: "As we indicated from the start, there was no merit to the lawsuit. We are pleased it was voluntarily dismissed by Dr. Tilzer after it was clearly demonstrated the lawsuit had no factual or legal merit."

The dismissal came following a court response by KUMC/Hospital arguing that the Kansas whistleblower statute exempts the hospital from the provisions of the Kansas whistleblower statute under which Tilzer filed his lawsuit.

The KUMC/Hospital statement also said it had "followed our routine practice for surgeons to fully inform patients of their diagnoses and treatments... In order to respect our patient's privacy, it would be inappropriate for us to discuss specifics of any patient situation." TDR

*—Joseph Burns*

*Contact Michael McCauley at 415-431-6747 or mmccauley@consumer.org.*

# INTELLIGENCE

## LATE & LATENT

*Items too late to print, too early to report*

Molecular and genetic testing laboratories that use the Microsoft Excel software program for some of their homegrown informatics may be at risk of lab testing errors due to an auto-correct quirk in the Exel software. *Modern Healthcare* reported on how researchers in Australia looked at 3,600 genetics papers. They determined that use of Microsoft Excel was the source of errors in about 20% of these papers. *Modern Healthcare* said that these errors happened "when the symbols used to denote genes in scientific literature are misinterpreted as dates or other numbers. For example, the gene Septin 2 is usually referred to as SEPT2. Excel automatically assumes the person inputting the number means the date of Sept. 2 and stores that in the field."

### MORE ON: *Genetic Testing Errors*

Researchers accessed the supplementary files containing the list of genes involved in the research for each of the 3,600 studies. This autocorrect feature of Excel cannot be turned off. It means that—to avoid such errors—a genetic testing lab entering this type of data must go back and change every field separately. Researchers also noted that it was about 10 years ago when this problem with gene data in Excel was first noticed.

### SONORA QUEST HAS NEW DRAW SITES IN SAFEWAY STORES

Apparently **Safeway**, the national grocery story chain, likes **Sonora Quest Laboratories** much better than **Theranos**. On August, 26, the two companies announced that the existing Safeway-Sonora Quest relationship would add SQL patient service centers to six more Safeway grocery stores in Arizona. Sonora Quest has operated PSCs in two Phoenix-area Safeway stores since November 2015. The relationship with Sonora Quest came about just weeks after *The Wall Street Journal* disclosed in October 2015, that Theranos had failed to deliver lab testing services to Safeway after the grocery chain had spent $350 million to build PSCs and lab testing rooms in 800 Safeway stories during 2012-13.

### TRANSITIONS

• In order to go fishing, Bill Pesci retired as Executive Director of Lab Services at **Baptist Health** in Jacksonville, Florida this summer. He now owns his own fishing charter business in Merritt Island, Fla., called **Blind Dog Charters**. During his career, Pesci worked with **Sonic Healthcare USA**, **Centura Health**, **Carolinas Healthcare System**, **SmithKline Beecham Clinical Laboratories**, **Dynacare**, and **Clinical Pathology Laboratories**.



***That's all the insider intelligence for this report. Look for the next briefing on Monday, October 17, 2016.***

## ★ SPECIAL SESSION! ★

# Health System Laboratory Is Living the Future of Lab Testing Today!

**Richard J. Zarbo, MD, PhD**
Chair, Pathology & Lab Medicine, Henry Ford Health

## How Henry Ford Health's Clinical Lab and Pathology Department Are Delivering More Value to Clinicians

It's been a 10-year journey for the laboratory at Henry Ford Health in Detroit to establish a Lean culture of continuous improvement and work towards standardizing lab testing and operational processes across the multiple hospitals in almost 40 laboratory sites within this large urban health system.

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# UPCOMING...

- ***Crunch Time for Labs on PAMA Market Reporting: Labs Report Many Problems with Gathering Data.***
- ***Follow-up on Use of Referencing Pricing to Cut Lab Test Prices: Which Major Payer Will Be Next?***
- ***Latest Developments involving Theranos, CLIA Sanctions, and Its Appeal with CMS.***

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