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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

Courts Uphold Labs' Challenges on CMS' Rules

SINCE MARCH 31, THE FEDERAL **CENTERS FOR MEDICARE & MEDICAID SERVICES** (CMS) has lost two decisions in two different U.S. district courts. Though each case addressed fundamentally different issues, the rulings were remarkably similar. In both cases, the courts questioned CMS' failure to properly use federal procedures. We provide analysis on both cases in this issue.

Each case has been widely reported. One involves the three San Diego-area laboratories which went to federal district court and filed suit to prevent CMS from moving forward with the Medicare Laboratory Competitive Bidding Demonstration Project in the San Diego-Carlsbad-San Marcos metropolitan statistical area (MSA). *(See pages 3-7.)* The second case was filed in the U.S. District Court in Washington, DC, by anatomic pathology condo/pod lab company **UroPath, LLC**, and its affiliates, seeking to delay and overturn implementation of the anti-markup rule that became effective on January 1, 2008. *(See pages 8-9.)* Since March 31, judges in both federal court cases have ruled in favor of the plaintiff laboratory organizations.

This is instructive on several points. For one, every time labs seek redress through CMS' administrative procedures, invariably the administrative judge rules against the laboratory and in favor of CMS. Thus, it is significant that two federal district court judges, in courts 3,000 miles apart, both slapped the government on the hand and granted the request for injunctions by the plaintiff labs.

Next, each judge's ruling has a common theme: In the San Diego case, the judge ruled that CMS was required to follow the notice and comment requirements of the Administrative Procedure Act (APA) of 1946 as it developed the Medicare Laboratory Competitive Bidding Demonstration Project. In the Washington, DC, case, the federal judge ruled that CMS was required to follow the notice and comment requirements of the APA when it proposed regulatory changes using the 2008 Medicare Physician Fee Update process.

These two federal judges have delivered justifiable setbacks to the bureaucrats at CMS. It is a message to CMS that it is not above the law! Further, as you will read elsewhere in this issue, these two federal court cases may establish a welcome precedent that CMS must follow APA requirements on *every* competitive bidding demonstration that it wants to implement. Be forewarned, however: neither of these federal court cases is concluded and government attorneys have yet to respond to the injunctions in both cases. TDR

Three San Diego Labs Stop Competitive Bid Demo

Federal judge issues injunction preventing CMS officials from proceeding with demo pilot

CEO SUMMARY: Last Tuesday, a federal judge handed a big court victory to the three plaintiffs in their lawsuit seeking to delay or stop implementation of the Medicare Laboratory Competitive Bidding Demonstration pilot in the San Diego area. In his written opinion, the judge ruled in favor of the plaintiffs on three key points and issued a preliminary injunction. It is now up to federal attorneys to respond to the judge's decision.

IT WAS BIG NEWS LAST TUESDAY when a federal judge issued a preliminary injunction that effectively stops the Medicare Competitive Bidding Demonstration from proceeding in the San Diego-Carlsbad-San Marcos metropolitan statistical area (MSA). Now comes the question: what does this decision mean for the laboratory industry?

The injunction ordered by U.S. District Court Judge Thomas J. Whelan of the Southern District of California on April 8 enjoins the federal **Centers for Medicare & Medicaid Services** (CMS) from:

1. *Announcing winners in the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project for the San Diego-Carlsbad-San Marcos Metropolitan Area;*
2. *Otherwise implementing and carrying out the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project for the San Diego-Carlsbad-San Marcos Metropolitan Area; and,*
3. *Further disclosing any information included in the bid applications submitted in connection with the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project for the San Diego-Carlsbad-San Marcos Metropolitan Area.*

"The judge agreed on a lot of points we made in this case," commented attorney Patric Hooper of **Hooper Lundy & Bookman** in Los Angeles. Hooper represents the three San Diego laboratory organizations that sued CMS: **Sharp Healthcare**, **Scripps Health**, and **Internist Laboratory**.

"The single most important element is that the judge decided there was no *per se*

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exception for Medicare demonstration projects from the rule-making requirements of the Administrative Procedure Act (APA) of 1946," Hooper explained. "That is significant, and not just for the laboratory industry. The judge's decision may have major implications. That's because, at an earlier phase in this case, the U.S. attorney argued in court that CMS has developed many demonstration projects and never goes through rule making. At that time, the judge didn't say a word in response to the U.S. attorney's statements.

San Diego Judge's Ruling May Help Repeal of Law

"ANOTHER BENEFIT TO THE DECISION in the San Diego Medicare laboratory competitive bidding case is that it gives us breathing room to get Congress to put a stake through the heart of the laboratory competitive bidding demonstration project," declared Alan Mertz, President of the American Clinical Laboratory Association (ACLA) in Washington, DC. "In fact, the judge's decision bolsters our arguments, and legislation to repeal the project is gaining steam in Congress."

Legislation introduced in the U.S. House of Representatives (HR 3453) has 40 bipartisan co-sponsors. A similar Senate bill (S. 2099) has eight bipartisan co-sponsors.

"The judge was crystal clear in finding that both laboratories and patients could be hurt," Mertz added. "ACLA applauds the court for recognizing the harm this project will cause and for highlighting the fatal flaws in this project. Now it is time for Congress to finish the job and repeal this ill-conceived project.

"Senator Max Baucus (D-MT) has said he intends to move a Medicare package to the floor of the U.S. Senate early next month," Mertz continued. "We are urging Congress to include our legislation to eliminate the demonstration project in that Medicare package."

"Clearly, CMS got themselves into a fix on this issue," Hooper added. "We believe that, if we are successful on this issue of rule-making, it could create a precedent because there should be rule-making as prescribed under the APA." The APA describes how federal agencies propose and establish regulations and establishes a process for federal courts to review agency decisions.

"For example, accept this precedent and it means that CMS must now follow APA rules," he said. "In the case of the laboratory competitive bidding demonstration project, CMS would now be required to inform the public in the San Diego MSA and hold hearings there as well.

"That's how it should be," he went on, "since, if Medicare officials want to experiment on Medicare beneficiaries, the entire process should be opened up so that doctors, Medicare beneficiaries, and other members of the public can have input. That's the rule-making process. CMS decided it wasn't going to do so, but the judge said he didn't see any reason why CMS shouldn't follow the rules."

It is likely that federal attorneys are reviewing the judge's decision. "This is a preliminary injunction, which means the government can abide by the ruling and go through rule-making," Hooper commented. "Or, CMS could abide by it but file an appeal with the Ninth Circuit Court of Appeals in San Francisco.

"A preliminary injunction can be appealed immediately. But, unless the government seeks a stay order, the appeal would have no effect on Whelan's decision, and an appeal could take months to resolve," he added. "Practically speaking, it will take them a while to analyze the decision. If they decide to appeal to the Ninth Circuit Court, they will need the approval of the U.S. Solicitor General.

"Among the hurdles the government faces is that Whelan is not some wild-eyed judge," Hooper said. "He's a conservative federal judge, who issued a decision that might be very difficult to overturn on appeal."

Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA) agreed that CMS has significant hurdles to overcome. "We're quite pleased about this decision," he stated. "Judge Whelan truly understood the issues and the possibility of the harm that the demonstration project could cause to labs and to Medicare patients. If CMS must now go back and follow all the rule-making procedures, it will be a complex process that takes time.

Legislative Solution Eyed

Commenting on the court decision during a meeting at ACLA's offices last Wednesday, Marc D. Grodman M.D., President of **Bio-Reference Laboratories, Inc.**, of Elmwood Park, New Jersey, and incoming Chairman of ACLA, said, "Right now, the government can do nothing and wait for a hearing on a permanent injunction or they could decide to appeal this decision. In all likelihood they will not appeal and there will be hearings and discovery on whether to make this a permanent injunction. All of that could take months. The point is that this issue will require a legislative solution and this court decision is an absolute endorsement of the position that the entire industry has been talking about for months, that repeal is necessary.

"Quite frankly when we have discussed this issue with members of Congress, we found support in favor of the industry position among congressional members and we found no support in favor of the laboratory demonstration project," Grodman continued. "This court decision is simply an endorsement of what everyone has been saying, and it will likely lead to strengthening our support to get a permanent solution."

As CMS moved to implement the demonstration project, THE DARK REPORT has been critical of the procedures CMS followed. In a special issue devoted to the Medicare Laboratory Competitive Bidding Demonstration Project, THE DARK REPORT explained in detail many of the steps CMS failed to follow. *(See TDR, December 31, 2007.)*

Federal Attorneys Had Tough Week on Lab Cases

LAWYERS FOR THE federal Centers for Medicare & Medicaid Services (CMS) had a tough time in the past few weeks in cases involving laboratory testing services.

First, on March 31, U.S. District Judge Rosemary M. Collyer granted a temporary injunction stopping CMS from implementing the anti-markup regulation that affected only anatomic pathology condo/pod labs. That was a legal victory for **UroPath, Inc.** and its affiliates, in the lawsuit they had filed in federal district court in Washington, DC. (*See pages 8-9.*)

Next, CMS lost an important decision on Friday, April 4, when U.S. District Judge Thomas J. Whelan agreed to hear arguments from three San Diego laboratories in their case against CMS. That ruling meant that Whelan would hear arguments from the labs for a preliminary injunction against CMS for implementing the Medicare Laboratory Competitive Bidding Demonstration Project in the San Diego-Carlsbad-San Marcos metropolitan statistical area (MSA).

Then, on April 9, Whelan issued the most significant decision in that case so far when he basically agreed with the arguments of attorney Patric Hooper of Hooper Lundy & Bookman in Los Angeles and issued the preliminary injunction. Hooper represents the three San Diego labs that sued CMS: Sharp Healthcare, Scripps Health, and Internist Laboratory.

Now several of those same procedural issues are at the heart of the court's decision, raising previous questions about whether CMS will go be able to go forward with this project in the coming months. **TDR**

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April 4 Fed Court Ruling Opened Door to Injunction

➤Three San Diego labs had to first prevail on three legal issues for their case to proceed

➤➤CEO SUMMARY: Federal Judge Thomas J. Whelan's ruling on three key legal points on Friday, April 4, was the first court victory needed by three San Diego-area labs in their lawsuit to prevent the Medicare Laboratory Competitive Bidding Demonstration in San Diego from proceeding. Judge Whelan ruled that the three plaintiff labs: 1) did not have to exhaust administrative remedies before turning to court; 2) a judicial review of these claims is not barred by law; and, 3) standards for ripeness and standing are met.

LAST TUESDAY'S DRAMATIC DEVELOPMENTS THAT STOPPED the Medicare Laboratory Competitive Bidding Demonstration Project from proceeding in San Diego would not have occurred without an earlier favorable decision by the federal judge hearing the case.

On Friday, April 4, U.S. District Court Judge Thomas J. Whelan ruled in favor of the three plaintiff laboratories on three key points. It was necessary for **Sharp Healthcare**, **Scripps Health**, and **Internist Laboratory** to prevail on these three points before Judge Whelan would then take up the primary issue in the case: the request by the three plaintiffs for a preliminary injunction to stop the **Centers for Medicare & Medicaid Services** (CMS) from moving forward with the Medicare Competitive Bidding Demonstration Project unfolding in the San Diego-Carlsbad-San Marcos metropolitan statistical area (MSA).

When requesting the preliminary injunction in January, Sharp Healthcare, Scripps Health, and Internist Laboratory challenged the procedural steps that U.S. Department of Health and Human Services (HHS) Secretary Michael Leavitt used to implement the bidding demonstration project. Because the judge initially ruled against the three laboratories on February 14, the Medicare lab competitive demonstration pilot went forward as announced. On February 15, CMS accepted bids from laboratories seeking to participate in the demonstration project.

➤Awaiting the Next Steps

As part of his February 14 decision, Judge Whelan requested that briefs and arguments be made on three points of jurisdiction:

1) *Do Plaintiffs have to exhaust administrative remedies before pursuing their claims in federal court?*
2) *Is judicial review of Plaintiffs' claims barred under 42 U.S.C. § 1395w-3(10)?*
3) *Are ripeness and standing requirements met?*

In its response to the plaintiff's lawsuit, attorneys for CMS said that the Medicare Act precludes such suits because it requires aggrieved parties to first file an administrative appeal. Second, CMS also argued that

the labs have no standing to sue because federal law does not apply to such challenges. On the third issue, CMS claimed any harm to the labs is speculative because no winners had been named in the bidding process.

Judge Gave Labs A Big Win

It was Friday, April 4, when Judge Whelan made his ruling after reviewing legal briefs from both sides. Whelan ruled that: 1) the court has jurisdiction over the labs' claims in the case; 2) the three plaintiff labs have standing in the case; and, 3) at least some of the claims are ripe for review, meaning the plaintiff labs could suffer damages.

Among the most significant statements in Whelan's 8-page ruling were those involving his decisions concerning arguments U.S. Health and Human Services Secretary Michael Leavitt had made in legal briefs. THE DARK REPORT reported on March 3 that the government had misrepresented the facts in arguing its case against the labs.

For example, federal lawyers for Leavitt argued that, if the three plaintiff labs are not named winning bidders, they can use HHS' administrative review procedures rather than pursue their case in court. Whelan found otherwise, writing in his ruling that "…contrary to the secretary's contention, if plaintiffs lose, they cannot submit claims to Medicare and, therefore, will not be in a position to obtain administrative review."

Whalen also said, "Furthermore, in a February 1, 2008, letter sent to [laboratory] providers, the secretary stated that non-winning laboratories cannot pursue administrative appeals... ('non-winner laboratories... have no appeal rights when Medicare denies payment for the test...') This statement contradicts the secretary's representation to the court that administrative review is available to plaintiffs."

Later in his order, Whelan said, "…plaintiffs contend that the secretary violated the Administrative Procedure Act ("APA") by enacting a rule requiring some laboratories that have a face-to-face encounter with the patients, such as plaintiffs, to participate in the competitive bidding process. Plaintiffs contend that this rule conflicts with the express language of [federal law], which excepts all entities that have a face-to-face encounter from the bidding requirement."

Leavitt had also argued that CMS' bidding structure explains which labs could submit bids. Whelan addressed this argument, writing, "But 'bidding structure' may reasonably be interpreted as encompassing only the secretary's establishment of the procedures or process that bidders must follow. In short, the term is ambiguous, at best, regarding whether it provides the secretary with unchecked discretion to determine who must submit bids. In light of this ambiguity, the court finds that the secretary has not provided 'clear and convincing evidence' that Congress intended to preclude judicial review of his interpretation of the face-to-face exception."

Labs' Arguments Have Merit

"The judge resolved these issues in our favor fairly convincingly," wrote attorney Patric Hooper of Hooper Lundy & Bookman in Los Angeles in an e-mail on April 4. Hooper represents the three labs.

"The easiest thing for the judge to have done in this case would have been to get rid of it on jurisdictional grounds," Hooper explained. "Given the complexity of the jurisdictional issues, we think this order, in itself, is a significant victory."

Had Judge Whelan not ruled in favor of the three plaintiff laboratories on these three points on Friday, April 4, then the court case would not have proceeded to the next step, which was the judge's decision about granting the injunction to stop the Medicare Laboratory Competitive Bidding Demonstration project, as requested by the plaintiffs. Just four days later, Judge Whelan did grant the temporary injunction. TDR

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Litigation Update

Federal Judge to Look at CMS Rule-Making in Anti-Markup Case

THERE'S BEEN WIDESPREAD INTEREST across the lab industry to news that on March 31, **Uropath, LLC**, won a preliminary injunction in its case to prevent the federal **Centers for Medicare & Medicaid Services** (CMS) from implementing an anti-markup regulation for pathology services performed at anatomic pathology (AP) condo (or pod) laboratories.

However, the injunction was not issued as a result of a ruling based on a hearing of the evidence that both sides presented. Rather, U.S. District Court Judge Rosemary M. Collyer's March 31 order for a preliminary injunction is specifically to allow the court more time to hear evidence and study the case. As the judge noted in the March 31 ruling about the origins of the case:

> *Plaintiffs move for a preliminary injunction; HHS [Health & Human Services] opposes and also moves to dismiss for lack of jurisdiction. In order to permit time for briefing and oral argument on the complex issues involved, the parties consented to an Interim Order, entered February 8, 2008. The Interim Order set a briefing schedule (with briefing completed on March 19, 2008) and a hearing on March 28, 2008. The Interim Order further provided that Secretary would not apply the Anti-Markup Rule...*

Court Wanted More Time

It was at the March 28 hearing that Judge Collyer declared that the court would need more time to study evidence and conduct hearings before ruling on the HHS move for dismissal and on the merits of the plaintiff's claims. Collyer proposed that both parties extend the status quo. However federal attorneys wanted to reserve the right to recoup any Medicare payments in excess of the amounts that would be permissible under the anti-markup rule for any such claims submitted between April 2 and May 2. The proposed status quo extension and interim order was to expire on May 2.

Granting The Injunction

Judge Collyer saw through that stratagem. It was one reason why she issued the preliminary injunction, stating in her written memorandum "Because the Secretary insists on retaining the right to recoupment, the Court finds that, for the purpose of delaying a ruling on the Plaintiffs' motion for preliminary injunction, the Secretary has not sufficiently waived its right to implement the Anti-Markup Rule. Accordingly, as explained below, the Court will grant Plaintiffs' motion for a preliminary injunction."

The immediate outcome of this preliminary injunction is that the plaintiff Uropath and its subsidiaries, **Atlantic Urological Associates, PA**; **Urology Care, Inc.**; **Urology Center of Alabama, PC**—as well as other laboratories that physician groups operate—can continue to file claims with the Medicare program for pathology services provided in these AP condo (pod) laboratories.

Three other issues bear watching. First, the judge's opinion indicates that she will review comments from the public to CMS, as well as internal records bearing on CMS' decision to delay implementing anti-markup rules for other clinical services, but not pathology. The judge's opinion indicates that, to date, federal attorneys have not produced such records.

Second, Collyer noted in her opinion that she has yet to decide whether she has jurisdiction to hear the case. If she decides she does not have jurisdiction, then UroPath's case may be dismissed and the temporary injunction would be lifted

Third, Collyer determined that the plaintiffs showed a likelihood of success by presenting evidence in support of their allegation that the final rule is arbitrary and capricious.

Public Notice And Comment

In particular, the judge noted that the notice and comment requirements of the federal Administrative Procedure Act (APA) *do* extend to the amendment and repeal of regulations, and that CMS issued the final rule without notice and comment. CMS also did not compile a record of the public comments that it received relating to its decision to change the rule.

In explaining her decision to grant the preliminary injunction to UroPath and the other plaintiffs, Judge Collyer addressed three distinct legal aspects:

[First factor] The court based its decision primarily on the issuance of the final rule (postponing the anti-markup rule except for anatomic pathology services performed in a centralized building and the technical component of purchased tests) without notice and comment as required in order to modify the regulation, as well as the failure of CMS to agree to delay enforcement of the rule for an additional month (until May 2, 2008) while the court reviews the case. On February 8, 2008, CMS and the plaintiffs had consented to an interim order providing that CMS would not apply the anti-markup rule for claims submitted between February 1 and April 1, 2008.

The Secretary issued the Final Rule without notice and comment. Further, while the Secretary admits that it issued the Final Rule pursuant to "informal" comment, no record indicating the nature and substance of such comments has been presented to the Court for review. The Court thus finds that this constitutes evidence in support of a finding of arbitrary and capricious rulemaking, evidence sufficient to support a preliminary injunction.

With regard to the second factor, Plaintiffs have demonstrated irreparable harm. Although the Secretary claims that this is merely a "benefits" case and that Plaintiffs can be made whole with a monetary damage award, such is not the case. Plaintiffs have shown that it is likely that Uropath and Dr. Michaels will lose their businesses if the Anti-Markup Rule goes into effect. The Physician Groups have shown that it is likely they will lose a substantial portion of their businesses and that they will be forced to close their laboratories. A preliminary injunction avoids such irreparable harm.

As for the third factor, there are no other interested parties who will be affected by the issuance of an injunction in this case. The Secretary will not be harmed as an injunction will merely maintain the status quo.

Finally, with regard to the public interest, public policy favors fair and open agency rulemaking. Therefore, issuance of a preliminary injunction is in the public interest... In sum, Plaintiffs have shown a likelihood of success on the merits, and the Secretary will not suffer significant harm if the injunction is granted. The balance of harms favors the Plaintiffs, and public interest favors the issuance of an injunction. Accordingly, the Court will grant Plaintiffs' motion for preliminary injunction.

Same Issue in Two Cases

THE DARK REPORT observes that Judge Collyer appears to be interested in whether CMS has properly followed the notice and comment requirements set out in the Administrative Procedure Act. If true, that would put this federal case on common ground with the federal case being heard in San Diego involving the Medicare Laboratory Competitive Bidding Demonstration Project.

Like Judge Collyer in Washington, DC, the federal judge in San Diego is reviewing whether CMS must follow APA notice and comment requirements as it designs and implements the Medicare laboratory competitive bidding demonstration project. That makes for interesting speculation. Were the plaintiff laboratories in both federal courts to win favorable rulings on this point, that might establish a very powerful legal precedent that CMS must follow. TDR

Hospital Lab Evolves Into A Consultative Resource

➤Hospital-wide initiative to educate clinicians on lab test utilization leads to improvements

➤➤CEO SUMMARY: Every laboratory recognizes it has the knowledge and expertise to become more of a consultative resource to its referring physicians. At 248-bed J.T. Mather Hospital in Port Jefferson, New York, the laboratory director took advantage of adminstration's interest in improving laboratory test utilization by creating an enriched program of education and collaboration. The effort has paid off, as measured by changes in lab test ordering patterns for targeted assays.

EFFECTIVE UTILIZATION of laboratory tests is widely recognized as one path to improved healthcare outcomes. It also helps conserve resources for hospitals and laboratories alike.

But, as every laboratorian knows, it's a tricky path to interact with physicians and help them do a better job of ordering the right test. Physicians frequently consider advice on lab test ordering to be an intrusion into their practice prerogatives.

That's why recent improvements in lab test utilization at **John T. Mather Hospital**, in Port Jefferson, New York, are instructive in how hospital laboratories can successfully collaborate with referring physicians to utilize lab tests in ways that raise patient outcomes while saving money for the hospital.

➤Twin Trends Fuel Test Demand

"About two years ago, our hospital administrators recognized that regional growth and changing patient demographics were squeezing our resources," stated Denise Uettwiller-Geiger, Ph.D., DLM(ASCP), Director of Laboratory Services at Mather Hospital. "Among other things, this led to a stated goal of improving how laboratory tests were ordered and how physicians responded to the results of these tests.

"This effort is particularly important because we do almost 2 million tests per year for this hospital, which is a 248-bed facility," Uettwiller-Geiger explained. "Our primary service area is Suffolk County, an area of Long Island undergoing rapid growth. Currently, about 1.4 million residents live in our service area and this number increased by 100,000 since the last census.

"Such rapid population growth means that the demand for lab tests is growing at a high rate," she said. "At the same time, the hospital has experienced a shift in patient demographics to an older, frailer population that requires more resources from the healthcare system. Both factors were driving up test volumes.

"We know that the lab plays a critical role in care and patient safety by providing timely test results to clinicians," Uettwiller-Geiger added. "However, the questions that come up are these: Are all these tests medically necessary? Are they appropriate? Are there better choices?

"As our administration took steps to better align use of resources in response to the trends of increased patient demand and growth in lab testing volumes, I saw this as an opportunity for our laboratory to increase its contribution and become an integral member of the healthcare delivery team," she observed. "This is particularly appropriate at this time, given the increasing complexity and sophistication of laboratory testing and technology. In other words, there was an opportunity for us to become more like consultants to our physicians."

Right Test At The Right Time

The laboratory at Mather Hospital launched a special effort to improve lab test utilization and effectiveness. Uettwiller-Geiger and her team has achieved these goals by working closely with physicians to develop a consultative role for laboratorians. It involves educating physicians about how to order the right test at the appropriate time for each patient.

"One way we manage resources is by totaling all the costs saved when we reduce the number of send-out tests," Uettwiller-Geiger said. "We also periodically monitor the number of reference lab tests sent out to identify the change in physician ordering patterns since the start of this test utilization effort two years ago.

"The thyroid panel is a good example," she noted. "In the past, physicians would routinely order a thyroid-stimulating hormone (TSH), tri-iodothyronine (T3) free, and thyroxine (T4). In 2004, physicians ordered more than 3,500 of those tests. Recently, we discontinued that thyroid panel and suggested that fewer tests might be appropriate. In 2007, our physicians ordered only 1,000 of those tests. We attribute this improved result to the education provided to the physicians about what tests would be most appropriate for each patient.

"Here's another example," Uettwiller-Geiger continued. "We believe physicians should order screening tests before using more sophisticated molecular tests. With Lyme disease testing, which is done frequently here in the Northeast, the screening test should come before a Western blot test. In addition, these are the guidelines of the federal Centers for Disease Control and Prevention, in Atlanta.

"But many times, physicians order every lab test they think they might need because they are seeing the patient as a consultant on the case," she observed. "We understand they want to look at everything. But it's much wiser to proceed in a more stepwise fashion.

"That's why we developed algorithms jointly with our physicians," explained Uettwiller-Geiger. "For instance, we have an algorithm for hepatitis B and C testing. Before we had the algorithm, doctors ordered everything from A to Z—and not all of these lab tests were necessary. Since everything has a cost and their time has a cost, we recommended that physicians start with a set number of tests and then, based on those lab results, move to the next level.

Cardiology Lab Order Guide

We also developed a chest pain sheet for physicians in our emergency department (ED)," she added. "We have four levels of care for patients who present in the ED for chest pain assessment. Included in the four levels of care is a lab test order sheet that was developed by the lab in collaboration with the hospital's heart team. This sheet provides physicians with more precision in how to order the most appropriate lab tests for each patient.

"Over the past year, we worked closely with cardiology on a number of initiatives," continued Uettwiller-Geiger. "That interaction gives us important visibility within the hospital and has opened up dialog with all physicians. Our first collaboration with the cardiologists involved developing an information sheet on the D-dimer assay. This is used as a marker of thrombotic process. The resulting fact sheet explained the definitions of clinical sensitivity and specificity for the test.

"Recognizing that physicians may not get this information from any other source, our lab test fact sheets incorporate references and data on the clinical significance, predictive values, and what the results from each particular test can tell them," said Uettwiller-Geiger. "These lab test fact sheets also describe the testing platform and the methodology used in our laboratory. Physicians tell us that they carry these fact sheets with them and refer to them regularly.

"Each of these education efforts creates an opportunity for laboratorians to converse and interact with physicians," she explained. "We developed these initiatives over the past 12 to 18 months and in that time, the lab staff has begun to serve more as a consultant throughout the hospital," she said.

"In fact, that's how I view my role: as a consultant to physicians. The change is noticeable," she added. "Physicians now regularly call the lab for consultations and for discussion about which specific tests they should order. Each one of these situations represents an opportunity for laboratorians to demonstrate their knowledge, increase their visibility, and ensure that the lab is seen as a valuable consultative resource.

➤Concise Source of Lab Info

"In our hospital, we work collaboratively with the physicians, and our experience and background is particularly useful when discussing difficult patient issues that arise in the course of treatment," stated Uettwiller-Geiger. "Often, I will consult with our Laboratory Medical Director John Chumas, M.D., and between the two of us, we can answer most any question that might arise from the physicians about what is the most effective test to use when treating patients and what results physicians might expect from those tests."

THE DARK REPORT observes that Uettwiller-Geiger is on the cutting edge of laboratory medicine today. She recognizes that it is difficult for physicians to stay up to date with the rate of development in laboratory services. As a result, laboratorians have more of an opportunity than at any time in the past to serve as consultants to physicians, thus increasing their visibility and the importance of having laboratory information at the point of care.

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Use of Lab Alert Facts Sheets Helps to Update Clinicians

HELPING CLINICIANS ADOPT new diagnostic tests and reduce their use of older, less effective lab tests is always a challenge. On February 2005, the John T. Mather Hospital laboratory issued an alert to cardiologists and other physicians about new diagnostic markers for myocardial ischemia and injury. The alert explained some of the changes the lab had instituted in an effort to improve patient care.

The alert bulletin highlighted Troponin I, along with Mather Hospital's adoption of Ischemia Modified Albumin (IMA) for ischemia. "We made changes in our cardiac marker testing to reflect the changing standards, the alert explained. "We have removed the 'cardiac enzymes' panel entirely. If you write an order for 'cardiac enzymes,' your order will be automatically changed to 'Troponin I every 6 hours x 3.'

"We are still experiencing physicians expecting Total CK / CK-MB and myoglobin to be measured as part of a 'cardiac enzyme' panel," the alert added. "While these tests are still individually available, they are not a part of any panel and are considered to be below the standard of care for evaluating myocyte death in the U.S. and Europe where we have Troponin I testing.

"Please remember that no biomarker should be used outside the context of clinical findings," the alert explained. "We want to be sure that you are aware of lab changes as we go forward. Nurses or clerks will be instructed to remind you and prompt you for more specific orders if a 'cardiac enzyme' panel is ordered."

Learn More about Mather Hospital's Lab Test Utilization Initiative

Denise Geiger, Ph.D., will speak at the upcoming* Executive War College *in Miami on May 13-14, 2008. Details at www.executivewarcollege.com

Lab Automation Viewed As Essential Solution

Automated systems help lab boost efficiency as a strategy to meet lab workforce challenges

CEO SUMMARY: A merger of three hospitals in Harrisburg, Pennsylvania, forced PinnacleHealth's lab director to find new ways to increase efficiency. A lab automation project helped improve turnaround time and staff productivity and cut costs. The cost savings is about 50 cents per test, which means the lab automation project is saving more than $1 million in annual operating costs. The key to getting the project approved was the savings on cost per test and having a proposal that matched the hospital's strategic plan.

LABORATORIES CONTINUE TO LEARN new lessons in how to use automation. That's certainly the case at **PinnacleHealth**, in Harrisburg, Pennsylvania, where a carefully-planned integration of new instruments and lab automation triggered impressive gains in quality, productivity, and cost savings.

"Automating as many processes as possible is one key for laboratories seeking to survive well into the future," advised Judith Darr, Administrative Director of Laboratory Services at PinnacleHealth. Her laboratory decided on a strategy of "best of breed" in looking for analyzers, instrument systems, and automation solutions.

Since automating hematology and chemistry in PinnacleHealth's new core laboratory in 2005, Darr's lab has delivered improved turnaround time (TAT), staff productivity, and cut 50¢ from the cost of every lab test. For a lab doing five million tests (including 2.5 million billable tests) per year, that 50¢ per test is generating more than $1 million in savings each year.

These numbers validate the return on investment (ROI) projected by Darr back in 2003 when she proposed the automation project to PinnacleHealth's board of directors. The health system invested $11 million in construction costs for a new, off-site lab facility, along with $2 million in new instruments and automation.

"This presentation centered on three main points," noted Darr. "One, lab automation had to deliver performance consistent with the health system's service goals. Two, it had to meet ROI targets. Three, it had to demonstrate that automation would help our lab cope with the tight supply of medical technologists (MTs). Like most labs, demographics mean that we have an aging med tech staff that is steadily approaching retirement. Our view was that lab automation is an absolute necessity as a strategy to supplement a tight labor supply.

Final Consolidation Step

"We had two major business problems to solve with this project. One was the pressing need to develop a way to operate the laboratory even as the supply of trained staff continues to tighten. Another was to

Gap Seen in Lab Staff Supply and Demand

FOR PINNACLEHEALTH in Harrisburg, Pennsylvania, a major factor driving its lab automation project was the shortage of available labor, said Judith Darr, Administrative Director of Laboratory Services.

"With tongue in cheek, you might say that medical technologists are a dying breed," she explained. "Nationally, the gap between supply and demand is minus 32%. When we broke ground for this new lab in 2004, there were 31,500 open med tech positions throughout the United States.

"This national shortage is mirrored in our regional market," added Darr. "Some 46% of our technical employees are aged 50 or older, and 22% are 55 or older. Retirement looms for many of these individuals. The PinnacleHealth Board recognized the implications of these demographics and understood why automating chemistry, hematology, and other departments in our laboratory is a viable strategy to maximize the contributions of a limited labor force."

resolve the outdated and inefficient lab operation that resulted from the merger of PinnacleHealth in Harrisburg with **Capital Health System** in 1996, followed by the 1998 merger with the **Community General Hospital,** also in Harrisburg. Although it was inefficient to run three separate laboratories, we did so for about six or seven years.

"Today, we have three hospitals with 670 beds, multiple primary care clinics, and five lab draw sites in the community," she explained. " The lab outreach program represents about 30% our volume. We now operate two laboratories with 197 FTES, seven full-time pathologists and one part-time pathologist.

"The merger of the three hospitals in the late 1990s left us with different instrument systems across the three lab sites and much of this equipment was aging," Darr continued. "We needed to consolidate two city hospital labs and that consolidation would be the final component of the merger of the hospitals. The consolidation was necessary to eliminate facility obsolescence and inefficiency, improve low staff morale, and allow us to accommodate automation on a grand scale.

"In these labs, we had the wrong services at the wrong sites," she noted. "We needed more room and better equipment. Planning for the lab division makeover commenced in 2001. After much consideration, we opted to centralize laboratory services in 30,000 square feet in a new building connected to the main Harrisburg Hospital. It was the last piece of PinnacleHealth real estate in downtown Harrisburg and there was a lot of infrastructure under that land. So, that was an extensive project."

Having obtained board approval, Darr's team moved forward with decisions on laboratory layout, new diagnostic analyzers, and laboratory automation solutions. The team decided to pursue "best of breed" in its selection of analyzers and instrument systems.

➤ Seeking the Best Equipment

"Of course, high volumes make chemistry and hematology the most obvious candidates for automation," recalled Darr. "Following plenty of research and trips to vendors and other laboratories, we made our decision. We decided the combination that would best meet our needs was **Beckman Coulter's** chemistry and total lab automation system, Sysmex for hematology, and **CellaVision** for automated digital differentials.

"Many lab directors believe that, if you automate chemistry and urinalysis, you need to put hematology on the same system," observed Darr. "But we came to a

different conclusion. Because hematology is so different and its sample tubes are quite different from chemistry tubes, we didn't see the necessity of putting hematology on the same automated system as chemistry, particularly when we evaluated the needs of our lab against the analyzer choices in the marketplace.

"For automation, our needs were clear," she added. "We wanted an automated system that could handle all specimens automatically from preparation to delivery to the instruments without any intervention by med techs.

Dramatic Gains In New Lab

"Planning, approvals, and implementation required two years and the new laboratory went live on December 6, 2005," said Darr. "Since then, the results of our automation project have been dramatic. Median turnaround time (TAT) for emergency department (ED) specimens declined by 17 minutes while we accommodated an 11% increase in test volume. Via attrition, we reduced staff by 12 FTEs.

"PinnacleHealth has its own method for measuring staff productivity," she noted. "Prior to the new lab project, we were already very productive by this measure, rated at 100% to 107%. Once the automated laboratory came into operation, staff productivity increased to 121%.

"Another important benefit was the increase in staff safety, since automation of these processes means staff no longer touches samples," added Darr. "One of the most hazardous tasks in a lab is when a tech pops the top off a sample tube, creating an aerosol that could contain pathogens. Decapping is now handled by the automated system, along with centrifuging, aliquotting and delivery of tubes to the analyzers hooked onto the automated line.

Automated Storage Solution

"Once the tests are run, the automated system delivers the specimens to an easily accessible storage unit," Darr explained. "This automation set up saved one FTE. We no longer manually search for specimens when additional tests need to be run from a specimen. Now, many of the specimens for add-on tests can by retrieved from storage by the automated system and delivered to the analyzers without manual intervention by our med techs.

"There's another major benefit in addition to improvements in TAT, productivity, and safety," she explained. "We have a goal of consistency in our performance on behalf of patients and physicians. Consistency incorporates several elements, including doing tests the same way each time in the same amount of time. This is just as important as the speed with which you deliver results. For most tests, it takes us about 15 minutes to get the specimen and then about 12 minutes more to make the result available. If we produce our results in the same time every day, our laboratory gets fewer phone calls. That means our lab operates with fewer interruptions.

Pursuing Consistency

"In fact, fewer interruptions is another benefit: Our laboratory is very quiet, and that enables our techs to work continuously in a productive environment," she said. "That further enhances productivity because we don't have staff spending much of their day in a reactive mode. Consistency is appreciated by both our physicians and our laboratory team.

"Another measure of our success came about six months ago when consultants toured the lab and had few suggestions to offer for further improvements and efficiencies," Darr related. "They didn't know what else they could do for us.

"Looking ahead, I know that in our next step in lab automation, we want to automate coagulation, urinalysis differential reading, and more fully automate our blood bank, a project we are now researching," Darr said.

Using Middleware in Phlebotomy to Improve TAT On Morning Draws by Cutting Data Input Needs

FIVE YEARS AGO, consultants suggested a turnaround time goal that the laboratory team at PinnacleHealth in Harrisburg, Pennsylvania, considered to be almost unreachable.

"These consultants said the lab should have all our early morning testing finished by 8:00 a.m.," said Judith Darr, Administrative Director of Laboratory Services. "At that time, this seemed to be an impossible goal, as we were meeting the 8:00 a.m. goal for early morning draws only about 60% of the time.

"Our first strategy was to send more phlebotomists out to collect and start them earlier in the morning," she explained. "This did lift performance up to the high 70%—low 80% range. Then came the move into the new lab and the start-up of the automated line. Although there was a dip in the percentage of results released by 8:00 a.m., after about 60 days, that improved steadily, reaching 97%, a performance—a level we've sustained now for more than 18 months! Senior management and the physician staff have recognized this significant achievement."

Another strategy to help early morning draws was the use of information technology. "Once the laboratory automation was operational and running smoothly, we then implemented Collection Manager software (from **Sunquest Information Systems, Inc.**, in Tucson, Arizona) about 18 months ago," Darr added. "The software allows our phlebotomists to carry a bar code scanner and a small printer with them. Now, when they collect specimens, the patient's information is entered at the same time. This eliminates a step at accessioning. Then, specimens come to the lab through the pneumatic tubes and are placed directly on the automated line. We estimate that automating patient information at time of specimen collection saves an average of 17 minutes for each accession."

The experience of PinnacleHealth in consolidating and rationalizing their multi-site laboratory organization points to one of the most important drivers behind the increasing use of laboratory automation: the need to extend the productivity of medical technologists.

Darr pointed out the twin challenges facing almost every hospital laboratory in the United States today. First, a large proportion of the medical technologists are rapidly approaching retirement. Second, in an already-tight laboratory market, there are not enough medical technologists to meet current staffing requirements, let alone enough to replace retiring baby boomers.

Thus, it is significant that the laboratory team, administration, and the board at PinnacleHealth recognized that a well-designed laboratory automation project could ease the labor crunch in two ways. One, by substituting automation for manual steps in the work flow. Two, by automating work flow steps that extend the productivity of the medical technologists, allowing them to devote time to higher value responsibilities. **TDR**

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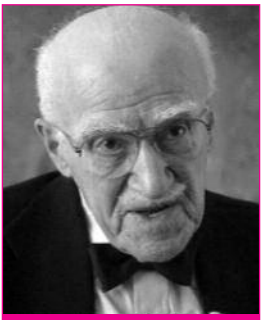
Notable People

Quality Guru Joseph M. Juran Dies Six Weeks Ago at Age 103

He recognized that a small number of problems generate most quality issues, coined "80-20 Rule"

He described the 20th Century as the Century of Productivity and expected the 21st Century to be the Century of Quality. Noted quality guru and management consultant Joseph M. Juran, Ph.D., died in his home in Rye, New York, on February 28 at the age of 103.

Juran was the second seminal figure in the quality management movement. He followed W. Edwards Deming, Ph.D., into Japan in the post-war years. Whereas Deming's strongest contributions were in the areas of statistical process control, Juran emphasized management's role in fostering quality. His thinking on quality control eventually evolved into the Juran Trilogy of planning, control, and improvement—all oriented to foster a company culture of continuous quality improvement led by management.



Joseph M. Juran
1904-2008

Published in 1951, his "Quality Control Handbook" eventually sold more than 1 million copies. He wrote the book while serving as Professor of Industrial Engineering at **New York University** (NYU).

Defined "Pareto's Law"

Laboratories using the "80-20 Rule" or "Pareto's Law" are working with one of Juran's fundamental concepts. Juran observed that, in almost every situation, a small number of problems were responsible for most quality complaints. He advised managers to identify and fix these "vital few" as a priority, rather than the "trivial many." His genius was to notice that statistical graphs highlighting this phenomenon looked very similar to the graphs produced early in the 20th Century by Italian economist Vilfredo Pareto in his work describing how, in Italy and other countries, 80% of the wealth was consistently concentrated among 20% of the population.

Work In Japan

Juran worked independently of Deming and first traveled to Japan in 1954 to teach quality management. His emphasis was teaching these concepts to middle and senior management. Juran's belief that top and middle management should be trained in quality management had been resisted in the United States. The opposite was true in Japan, where his seminars and programs consistently attracted CEOs and other senior executives.

The work initiated by Deming and Juran in Japan took about 20 years to pay off. By the 1970s, Japanese products began to capture major market share across the globe. During this decade in the United States, Japanese products in consumer electronics, automobiles, and copy machines were readily accepted by American consumers. American manufac-

turers saw their market dominance eroding and began to study why Japanese products were so successful.

At this time, in 1979, Juran founded the **Juran Institute.** It was auspicious timing, as the 1980s saw an explosion of interest in quality management. Companies in the United States and across the world began to study the quality principles of Deming and Juran.

For pathologists and laboratory managers who are keenly interested in quality management principles and their evolution, Juran's life includes another fascinating stop. After graduating with a B.S. in electrical engineering from the **University of Minnesota** in 1925, Juran took a job with **Western Electric** in the Inspection Department of the Hawthorne Works, located in Chicago, Illinois.

This sprawling complex employed 40,000 people. Walter A. Shewhart, a recognized pioneer of quality techniques, had worked at Hawthorne between 1918 and 1924. He then went to the parent company, **Bell Laboratories**, where he worked until his retirement in 1956. In 1926, a team of Quality Control pioneers was sent from Bell Laboratories to the Hawthorne Works to introduce a new program of quality control tools and techniques.

First Quality Department

Juran was one of 20 employees picked to undergo this training. Before long, Juran was one of two engineers running the Inspection Statistical Department. This was one of the earliest examples of a formal quality unit in American industry.

The Western Electric Hawthorne plant was a hotbed of quality control and statistical analysis of manufacturing processes. Management experiments conducted there at this time are still taught in business schools across the world.

Along with Juran and Shewhart, another interesting connection is that in the summers of 1925 and 1926, W. Edwards Deming also worked at the Hawthorne plant. But Deming and Juran did not meet at this time. It was not until the 1930s that the two men would meet. Although familiar with each other, their careers unfolded separately.

Juran's Concepts

Juran brought specific concepts to the quality management field. As noted by Morgan Witzel, writer for the **Financial Times:**

> *Juran defines quality as "the process of identifying and administering the activities needed to achieve the quality objectives of an organisation." He begins from two principles. First, managers have to realise that "they, not the workers, must shoulder most of the responsibility for the performance of their companies." Second, they must understand the financial benefits that can be realised once quality is made a priority.*
>
> *He thus turns quality into a management issue first and foremost. Improving quality, he says, requires a systematic, company-wide approach; piecemeal efforts by individual teams or business units will not work.*
>
> *Juran insists that quality is defined by the user, not the producer. If the customer does not perceive that a product has delivered good quality, then the company has failed. An assessment of quality, therefore, means that management must look outside the company as well as inside.*

Clients and longtime readers of THE DARK REPORT know the emphasis we place on management leadership as a linchpin to the clinical and financial success of clinical laboratories and pathology group practices. This is consistent with Juran's thinking. "It is most important that top management be quality-minded. In the absence of sincere manifestation of interest at the top, little will happen below," he said.

Although that quote sounds familiar today, it was written by Dr. Juran in 1945! It has taken the business world many decades to grasp the power of the insights developed by Juran and his peers. **TDR**

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Psychiatry may soon have its first set of objective clinical laboratory blood tests for mood disorders. Researchers at the **Indiana University School of Medicine** recently published their findings in *Molecular Psychiatry*. Working with 11 different genes, they described a "predictive score [that was] developed based on a panel of 10 top candidate biomarkers (five for high mood and five for low mood) [that] shows sensitivity and specificity for high mood and low mood states, in two independent cohorts."

MORE ON: Mood Disorders

These research findings show how new genetic technologies will soon provide psychiatry with more precise diagnostic tests. As this occurs, psychiatrists are likely to become significant sources of laboratory test referrals for the nation's clinical laboratories.

TRANSITIONS

• Jerry R. Goldsmith is retiring from the **American Association of Clinical Chemistry** (AACC) after 15 years of service. April 4 was his last official day at AACC, but he will continue to serve the association as a consultant. He has founded **Sandpiper Strategies** as his new enterprise. Goldsmith's energetic work on behalf of AACC and the entire lab industry has been widely recognized.

• Joe Perrone, Sc.D., joined AACC as its new Vice President of Strategic Initiatives and Business Development. He will assume many of Jerry Goldsmith's former responsibilities. Perrone was most recently at the **American Type Culture Collection**. He earlier worked with the **University of Maryland Biotechnology Institute** and **Becton Dickinson**.

• **Luminex Corporation** of Austin, Texas, recently named Randel S. Marfin to the new position of Vice President of Strategic Development. Marfin, who joined Luminex during its formation 11 years ago, has served in executive positions with **MetPath**, **Nichols Institute**, and **Damon Clinical Laboratories**. Luminex also announced that Gregory J. Gosch will be Vice President of the Luminex Bioscience Group while Darin Leigh will serve as Vice President of Sales and Marketing.

• **Laboratory Alliance of Central New York, LLC,** named Michael R. O'Leary, M.D., as its new Chief Executive Officer. Since the lab organization's founding in 1998, O'Leary has been Corporate Medical Director. O'Leary also serves on the Pathology Advisory Council of **The Joint Commission**.

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