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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

ACLA Files Appeal in Federal PAMA Lawsuit

There is an important new development in the lawsuit in federal court that challenges how the **Department of Health and Human Services** (HHS) is implementing the Protecting Access to Medicare Act of 2014 (PAMA). An appeal was filed by attorneys representing the **American Clinical Laboratory Association** (ACLA).

On Friday, Oct. 19, the ACLA's lead attorney on the case, Mark D. Polston of the law firm **King & Spaulding**, notified the court that the lab association would appeal the decision to the U.S. Court of Appeals for the District of Columbia Circuit. *(See TDR, Oct. 1, 2018.)*

The civil notice of appeal came almost 30 days after U.S. District Court Judge Amy Berman Jackson issued her Memorandum of Opinion in the case on Sept. 21. The ACLA will present its legal arguments in the case at a later date.

On Dec. 11, 2017, the ACLA filed the case in U.S. District Court for the District of Columbia against HHS Secretary Alex M. Azar. In the case, ACLA made compelling arguments that under PAMA, the HHS set clinical laboratory rates for 2018 based on a flawed data-collection process. When she dismissed the case last month, Jackson said the court lacked "subject matter jurisdiction" in the case. Under PAMA, clinical labs were precluded from challenging the rates set under the law, a provision Berman cited as a significant reason for rejecting the ACLA's arguments.

In the same ruling, however, Jackson acknowledged that the ACLA raised important questions about how the HHS implemented PAMA and those questions so far have been unaddressed.

ACLA had argued that HHS' rate-setting process was flawed because the HHS did not follow Congress' intent. Instead, it collected data on what private health insurers pay labs from only 1% of the nation's clinical laboratories, ACLA charged. ACLA believes important questions have yet to be answered and this appeal is intended to be the next step to have a higher court review the lower court's ruling relative to those points. The entire clinical laboratory industry has a stake in whether the ACLA finally gets its day in court over the specific issues it believes have not been addressed by Judge Berman. TDR

Are More Criminal Charges Coming in Theranos Case?

Federal prosecutors say criminal case is bigger than what was described in earlier indictments

CEO SUMMARY: As a going business, Theranos may have been dissolved in September, but it continues to be in the news. The biggest development was a disclosure in federal court earlier this month by federal prosecutors that there may be additional criminal charges to come that go beyond the indictments of former CEO Elizabeth Holmes and former COO Ramesh "Sunny" Balwani. Separately, a national news service reported that incomplete financial records were a factor in the firm's demise.

MORE CRIMINAL CHARGES may be coming in the criminal case the **U.S. Department of Justice** is bringing against **Theranos Inc.** Recent reporting is also revealing new details about the financial problems that caused the failure of Theranos.

The possibility of additional criminal charges surfaced during a hearing at the U.S. District Court for the Northern District of California on Oct. 12. That is when federal prosecutors in the case against the blood-testing company said the case is broader than what has been disclosed publicly to date.

In June, the DOJ filed criminal fraud charges against former Theranos Founder and CEO Elizabeth Holmes and against former company President Ramesh "Sunny" Balwani. In June, a grand jury returned an indictment charging Holmes and Balwani with two counts each of conspiracy to commit wire fraud and nine counts each of wire fraud. *(See TDR, June 18, 2018.)*

During that same hearing in court in San Jose, Calif., Holmes and Balwani sought to block the DOJ from going through more than 200,000 company documents. However, U.S. Magistrate Judge Susan van Keulen denied that request, according to reporting from Joel Rosenblatt of *Bloomberg News*.

Van Keulen ordered lawyers for both sides to find a way to review the documents while protecting confidential information from prosecutors. In her order, van Keulen referred to undisclosed "charges and activities" in the government's broad, ongoing investigation of Theranos. This suggests the government's

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case may extend beyond the activities of Holmes and Balwani.

Assistant U.S. Attorney John C. Bostic described the government's request for the documents as part of an ongoing investigation. He also said the indictment of Holmes and Balwani in June was "just an event in the ongoing investigation" and not the end of the investigation, Rosenblatt added.

During the hearing, Bostic said, "This story is bigger than what's captured in the indictment." Although the DOJ does not yet have particular targets, Bostic added that the indictment, "doesn't capture all the criminal conduct" the investigation has uncovered, Rosenblatt wrote.

"The ruling could give prosecutors additional leverage at trial or in any plea deal, including any potential agreement by one defendant of the former couple to aid the prosecution of the other," Rosenblatt wrote.

Attorney Jeffrey B. Coopersmith, a lawyer for Balwani, spoke for both defendants when he charged that the government was abusing its investigative powers by using the grand jury to make demands for information months after the indictment was filed on June 14. Last month, the DOJ revised the indictment slightly.

Coopersmith charged that the DOJ wanted to "storehouse" information to use later at a criminal trial by "saving up the acorns for winter, because they may find something," Rosenblatt explained. During the hearing on Oct. 12, the two sides sparred over more than 200,000 pages of Theranos' documents and e-mails from 2016 to 2017, he added.

Van Keulen asked the lawyers to work out a way to review the documents while shielding protected information from prosecutors and denied the defense's motion to limit the grand jury.

"As explained by the government at the hearing, and as evident from the record in this case, the government's investigation concerning Theranos is far-reaching, extends beyond the subject matter of the current indictments, and may extend beyond these defendants," Judge van Keulen wrote. The scope of the grand jury's investigation includes charges and activities that are not the subject of the Holmes and Balwani indictment, she added. Therefore, she allowed the government to continue to use the grand jury.

In her ruling, van Keulen explained that the government issued a subpoena for Theranos' documents in September 2017, nine months before the grand jury returned the original indictment in June 2018, and that Theranos has been producing documents since the subpoena was issued. "The parties' present dispute focuses on Theranos' final production of documents, which concerned the period October 2016 to September 2017, whereas the indictments relate to an earlier period," the judge wrote.

Judge's Ruling

"These facts support a finding that the subpoena and the government's continuing efforts to enforce the subpoena after the original and superseding indictments are proper," she added. "Defendants make much of the fact that the grand jury issued a superseding indictment in September 2018. However, defendants have failed to demonstrate that the timing of the relevant events renders the government's ongoing efforts to enforce the Theranos subpoena improper."

Among the more than 200,000 pages that the two parties will review are contracts Theranos had with dozens of companies and institutions, including: **GlaxoSmithKline Plc**, **Pfizer Inc.**, **Celegene Inc.**, **Novartis AG**, **Bristol-Myers Squibb Co.**, **Merck and Co.**, **AstraZeneca Plc**, the **Mayo Clinic**, **Stanford University**, and **Johns Hopkins University**, Rosenblatt explained.

In a court filing, the DOJ said it plans to turn over more than 12-million pages of documents to Holmes and Balwani as part of pre-trial information sharing. TDR

—Joseph Burns

In Struggle to Keep Going, Auditors Could Not Get a 'Clean Opinion' of Theranos' Financials

IN A DETAILED EXAMINATION of the financial challenges that Theranos Inc. faced over the past two years, *MarketWatch* revealed that producing a clean audit of its financial statements last year was a significant challenge that helped bring down the clinical laboratory company.

MarketWatch reporter Francine McKenna wrote, "The goal of the 2017 audit was to get a clean opinion on Theranos' financials." This means the auditors needed to be reasonably assured that the company's financial statements did not include a material misstatement due to error or fraud.

Doing so was challenging because the company had previously not tracked its fixed assets, such as its technology, equipment, or furniture, McKenna explained. For her research, McKenna quoted a number of sources, including Philippe Poux, who served as Theranos' final CFO.

Poux was at Theranos from November 2017 until last month. On his **LinkedIn** page, he said he was tasked to rebuild the company's core finance functions prior to the raising of a $100 million debt facility. Previously, he worked as a principal at the consulting firm **Booz & Co.** and as a director at the accounting firm of **Ernst & Young**.

When he arrived, Theranos had no budgeting process, no accurate cash-flow forecasting, and no auditable financial statements, McKenna reported. These facts are remarkable given that Holmes founded the company in 2003, and by 2014, it was valued at $9 billion.

Soon after arriving at Theranos, Poux helped to close a deal to borrow $100 million from **Fortress Investment Group LLC**, a division of **SoftBank**, McKenna wrote. In the deal, the private-equity firm became Theranos' most important creditor in part because the arrangement gave Fortress "a lien on all of Theranos' assets, including its portfolio of patents," McKenna explained.

But Fortress also required an independent auditor's opinion of the company's 2017 financial statements by June of this year. "Fortress released $65 million when the deal closed, with the rest contingent on achieving certain milestones, as well as the audit," McKenna wrote. If Theranos could not deliver a clean audit, it would have defaulted on the Fortress agreement, she added.

As Poux and others worked on the financial statements, it became clear that the company would run out of funds, McKenna said.

"To avoid the auditor's 'going concern' warning, Theranos needed to prove it would have enough cash to support itself for 12 months from the date of the audit report, which was expected to be in June," McKenna wrote. The Public Company Accounting Oversight Board says auditors' "going concern" statements are important judgments about whether a company has the financial resources to run viable operations for the next 12 months.

As the June deadline approached, Holmes was unsuccessful in getting investors to provide more financial support and failed to sell the company, McKenna explained.

As TDR reported last month, Theranos CEO and General Counsel David Taylor wrote an e-mail to the company's shareholders on Sept. 5, explaining that the company had only about $5 million in cash on hand and would distribute those funds to its unsecured creditors. That same day, *Wall Street Journal* reporter John Carreyrou wrote that the big-name companies that had invested in Theranos would get nothing. "All told, investors in Theranos have lost nearly $1 billion," he added.

Lab Market Update

Walgreens, LabCorp Announce Expansion of PSC Partnership

Within four years, LabCorp will go from having 17 PSCs in Walgreens stores to 600 such PSCs

TWO NATIONAL COMPANIES just signed the lab industry's largest agreement to put clinical laboratory patient service centers (PSCs) into retail stores. Earlier this month, **Walgreens Boots Alliance** and **Laboratory Corporation of America** announced plans to open 600 PSCs in Walgreens stores in coming years.

Since June 2017, Walgreens and LabCorp have opened 17 patient service centers in four states. In these sites in Colorado, Florida, Illinois, and North Carolina, the two companies say they are offering consumers easy access to healthcare services. The 17 current PSCs are located near the pharmacy areas inside Walgreens stores and are part of LabCorp's network of some 2,000 PSCs across the country.

Consumers' Response

"The primary reason for expanding LabCorp at Walgreens is that there has been a positive response from consumers and healthcare providers to the initial 17 locations," LabCorp said in response to questions from THE DARK REPORT. "These sites are meeting a strong demand for consumers to access quality, trusted lab testing services in a convenient location in the community."

In general, the 600 new PSCs will operate as most other LabCorp PSCs do, the company said. Specimens are collected for a broad range of testing, but certain services, such as drug screening, varies by location, the lab company said.

The two companies also may offer point-of-care services such as biometric screening, which is already provided in some LabCorp service centers, LabCorp added. In the future, LabCorp and Walgreens may offer some on-site testing in the LabCorp PSC at Walgreens sites, the company said.

LabCorp was not ready to discuss the locations of the new PSCs except to say they would be opened in markets nationwide. And, LabCorp did not have any additional information on when the new sites would be open.

For now, there will be no difference in price for testing performed at the already-operating PSCs, LabCorp said. Walgreens declined to answer questions about the partnership, preferring to let LabCorp address these issues.

It should be noted that Walgreens and LabCorp announced the addition of 600 new PSCs one day after **CVS Health**, another large pharmacy retailer, announced that the **Department of Justice** had approved its merger with health insurer **Aetna**. Reports show that Walgreens considers CVS to be one of its biggest competitors.

This PSC agreement between Walgreens and LabCorp supports a trend already identified by THE DARK REPORT to put PSCs in retails stores. *(See TDR, Oct. 30, 2017.)* Consumers prefer a store nearer to their home over having to drive to a hospital campus to provide their specimens. TDR

—Joseph Burns

Boston Heart Case Ruling Raises Questions for Labs

Legality of clinical lab marketing practices still to be decided after judge dismisses some claims

CEO SUMMARY: Is it a violation of federal healthcare laws when clinical labs pay physicians to mail specimens and/or forgive all or part of patients' copayments and deductibles? A federal judge's ruling in a lawsuit against Boston Heart Diagnostics last month dealing with these two actions created a precedent that could affect all labs. It means that clinical lab directors and their attorneys will want to follow this case closely to see how it concludes, according to a lawyer familiar with the issues.

THERE MAY BE MORE SIGNIFICANCE to a recent decision in a federal court case involving **Boston Heart Diagnostics** and compliance with federal healthcare laws than the points brought out by THE DARK REPORT in its coverage of that judge's ruling in the last issue.

"Your article in the last DARK REPORT on the September federal court decision in this case was very good and it alerted the industry to developments in what may or may not be further areas of fraud activity to be investigated and prosecuted," said attorney Jeffery J. Sherrin. "I think, though, that the case means a lot more for several reasons."

Judge's Ruling

Sherrin, who is President of **O'Connell & Aronowitz**, in Albany, N.Y., is referring to the case of the *United States of America ex rel. Chris Riedel vs. Boston Heart Diagnostics Corporation* and the judge's ruling that involved some of the practices outlined in the arguments the plaintiff made in the case, which could affect how clinical lab companies market their services to physicians.

Those practices include paying physicians packaging fees to facilitate sending specimens to the lab and waiving copayments and deductibles.

Sherrin wanted to emphasize a key fact about certain of the plaintiff's allegations of illegal marketing practices. "Even though some of the claims in the case were dismissed for deficiencies in the allegations the plaintiff made, that does not mean the practices outlined in those claims are automatically considered to be legal," Sherrin said. "It means—at least in this case—that the plaintiff failed to allege facts that were necessary for the claims to go forward. That could be the result of a pleading error, or it could be that the plaintiff did not possess facts necessary to move the case forward."

As THE DARK REPORT explained *(see TDR Oct. 1)*, a ruling in a case against Boston Heart Diagnostics last month could have far-reaching effects on clinical laboratories that pay physicians to mail specimens and/or that forgive all or part of patients' copayments and deductibles.

For that article, Justin T. Berger, an attorney representing the plaintiff in the

case against Boston Heart, explained that U.S. District Judge Reggie B. Walton issued a ruling Sept. 12 in which he both granted and denied in part Boston Heart's request to dismiss the complaints in the case. In the ruling, Walton thus decided that two legal theories in the case would go forward to trial, said Berger, a principal in the law firm of **Cotchett, Pitre & McCarthy, LLP**, of San Francisco.

Those two theories relate to practices that some labs use, including such practices as paying physicians packaging fees to facilitate sending specimens to the lab and waiving patients' copayments and deductibles in a manner that benefits the referring physicians.

The plaintiff in the case is the United States, through Chris Riedel, CEO of **Hunter Heart Inc.**, a clinical lab in Los Gatos, Calif. Riedel brought the case (*United States of America ex rel. Chris Riedel vs. Boston Heart Diagnostics Corporation*), as a whistleblower in 2012 and refiled it last year. Plaintiff is seeking money damages allegedly sustained by the Medicare program.

More Nuanced View

Although Berger said Walton's ruling essentially made the practices illegal, Sherrin has a more nuanced view.

"The claims that were dismissed were dismissed for deficiencies in the pleading, not because the court found that the practices would not be illegal," Sherrin said. "The case somewhat operates as a blueprint as to how the lawyers should plead the complaint in the next case, and there can be no comfort in the fact that the claims relating to several of the alleged schemes were dismissed.

"In this case, the judge sustained two major claims: waivers of copayments and inflated packaging fees," Sherrin explained. "But that also does not mean that Boston Heart was guilty of kickbacks. It means that the complaint adequately alleges what it had to allege in order not to be dismissed.

"Those practices—as they may have been employed by Boston Heart—still could be legal," he added. "What the court is saying is that the practices can be illegal if you are doing things that ultimately result in remuneration or compensation to the physicians and that compensation is made in return for referrals.

Legal or Illegal?

"But the very same conduct might not be illegal if it wasn't intended to induce referrals, the physicians were not remunerated, or the lab didn't know that what it was doing was or may be illegal," he said.

"Ultimately, a number of factors will go into whether a practice, such as waiver of copayments, is illegal," he said. "For example, the complaint alleges that the waivers of the patients' responsibility to pay copayments and deductibles benefited the referring physicians personally, because waiving those payments will increase the number of patients who want to use those physicians and make the physician's job easier. It is not at all clear that relieving a physician of the alleged burden of explaining payment responsibilities to patients would constitute unlawful remuneration.

"But now, the plaintiff, Riedel, has to prove—through discovery or during the trial itself—that not only were the patients' responsibilities waived routinely, but that waiver of responsibility was done with the intent to induce referrals and that the physician was remunerated as a result of waiving those responsibilities," he added. "Proving intent and showing that the intent resulted in remuneration may be difficult to establish.

Waiving Patient Fees

"In some cases, waiving of these fees could be a kickback, but in other instances, doing so could be a perfectly legal practice," Sherrin suggested. "It could be legal if a lab waives these fees not to induce physicians to refer specimens to you but rather to increase the amount of money patients must pay.

In Federal Court Case, Clinical Lab Firm's Board Member Became a Whistleblower

ONE ISSUE WORTH DISCUSSING from the case involving Boston Heart Diagnostics is the fact that the plaintiff in the case once served as a member of the lab's board of directors. As a result of serving on the board, he acquired information that enabled him to file a federal whistleblower case against the lab, said attorney Jeffrey J. Sherrin, President of O'Connell & Aronowitz, in Albany, N.Y.

The plaintiff who filed the original whistleblower case in 2012 is Chris Riedel, CEO of Hunter Heart Inc., a clinical laboratory company in Los Gatos, Calif.

"Because Chris Riedel was a member of Boston Heart's board of directors before he filed his case, it means that information he claims to have could have been acquired largely in his role as a director," observed Sherrin. "It should concern labs and other providers if board members can use information that they acquire in their fiduciary capacity as board members against their organizations.

"Board meetings are supposed to be open so that they allow for the full exchange of information and the expression of all opinions," he added. "And, of course, board members have a fiduciary responsibility. But the exchange of otherwise necessary information and opinions could be stifled at board meetings if members or key employees fear that other board members will use information acquired during board meetings against the company.

"I'm not saying that what Riedel did in filing this lawsuit is right or wrong," Sherrin added. "I'm only saying that it could have a negative effect on discussions during board meetings. That should be a concern for labs, and particularly for lab directors."

"In recent years, labs have found it difficult to collect copayments and deductibles from patients," he added. "Labs know, for example, that if they send a bill to a patient for $1,000, they may get nothing. But if that same lab sends a bill for $100, it may get paid $100.

"That's just one reason that labs would engage in pricing policies that have nothing to do with inducing a physician to refer specimens," he said. "If a lab wants to waive its copayment fees, we advise them that it should be patient-specific, not across-the-board; to do it directly with the patient; and leave the physician out of it entirely. That way, it is more difficult to prove that the physician has gotten remunerated in any way.

"What I'm saying is that when a judge grants a motion to dismiss, it just may mean that the plaintiffs did not make sufficient allegations that the practices in question were illegal," Sherrin said.

"Take the issue of speaker fees, for example. In this case, the judge said the complaint contends that the speaker fees paid by the defendent lab company were 'outrageous,'" continued Sherrin. "That could mean anything and it might have nothing to do with fair market value. It could just mean that the plaintiff believes that the doctor doesn't know what he's talking about and yet he's being paid this large fee.

"For these reasons, this case gives us a blueprint about what the plaintiff must argue and what the defense should contend on the other side," he concluded. "All of these issues are important for clinical labs to follow because, if this case goes to trial, Boston Heart may win the case. Or, Boston Heart also could lose the case. Either way, it will be a costly process." TDR

—Joseph Burns

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Medicare now posts every pathologist's prices

Medicare Data Makes Pathology Prices Public

CEO SUMMARY: Each year since 2015, Medicare officials have posted the prices charged by every physician. That now makes it possible for pathology group practices to conduct a price study of their region and state to learn how their group's prices compare with other pathology providers. A national pathology consultant points out that one way to use this data is to identify which services a pathology group has underpriced and overpriced.

For anatomic pathologists, the time approaches when patients, payers, and referring physicians can easily discover what each pathology group charges. Already, most hospital administrators know what pathologists charge, as do health insurers.

Soon, pricing data will be readily available to patients as well. When that happens, pathologists may want to publish their fees online and start competing more fiercely on price.

To help pathologists navigate the potential pitfalls of fee transparency, Robert Tessier, a Senior Reimbursement Consultant with **HBP Services** in Woodbridge, Conn., developed a pricelist based on Medicare data that offers significant insights.

"Medicare knows what pathologists are charging and is making that data available to the public," Tessier said in an interview with The Dark Report. "Soon, patients will also know what pathologists are charging and will start comparing prices.

"However, that is not today's reality," added Tessier. "I have yet to see any pathology group that publishes what it charges. That day is coming, but it is not here yet."

To prepare, Tessier recommends that pathology practice administrators do two things. First, become familiar with the Medicare physician price data available on the national **Centers for Medicare and Medicaid Services** (CMS) website that shows what every pathologist in the country charges by CPT code.

Second, use the data to compare pathology group fees within each state or local community.

"Pathology groups unaware of this data will be at a competitive disadvantage going forward, noted Tessier. "This Medicare data is easy to access and download from the CMS website. It can be sorted by state or address. Using this information, a practice administrator can find what other pathology groups charge.

"The reports we produce are limited to Medicare data provided by pathologists, not from laboratories," he explained. "Therefore, companies such as Quest Diagnostics, Inc. and Laboratory Corporation of America were not included.

"Also, the data we examined relate specifically to Medicare code 88305," stated Tessier. "This code represents a gross and microscopic examination of a specimen. In the Medicare database, there are six million records showing pathology payments for the professional component of 88305 and about 4.5 million records showing payments for in-office or facility billing for 88305s.

Alarming Discrepancies

"There is a good reason why it is time for pathologists to determine their ideal price point when dealing with hospital administrators, patients, and third-party payers," he added. "Thirty years ago, Medicare defined the prevailing rate for pathologists and other healthcare providers as being at the 75th percentile of what everyone charged. Since then, Medicare has moved away from having a single prevailing rate.

"For pathology clients, we have begun to use the Medicare data to assess their region and state and help them develop a smart pricing strategy that keeps their prices competitive, while at the same time helping them identify services they have underpriced and raise those up to current market levels," said Tessier.

"We now have statistical models showing charges at the 25th, 50th, 75th, and 90th percentiles," he added. "Using these numbers, pathologists can determine the prevailing rates in their areas. *(See chart on page 13.)*

"As the chart shows, rates vary widely from one state to another," he said. "A more granular look at these numbers shows that rates vary even among cities and towns.

"Another factor to consider is that the Medicare database includes both facility and non-facility fees," Tessier said. "The

facility fee is what pathologists charge for the professional component only. The non-facility fee is mostly identified as what they bill globally, meaning for both the professional component (PC) and the technical component (TC).

"Sometimes, practices will further complicate their charges for non-facility fees, which is why it's not often as simple as looking at a table to determine pricing," he added.

National Average for 88305

"At the top of the chart is the national average—meaning all the data on six million units of 88305, regardless of the state," said Tessier. "Once you know the percentile, it's possible to compare that with the individual charges in each state. So, for example, the 50th percentile in Arizona is only $98, but the 50th percentile nationally is $173. That's a significant difference, which pathologists in Arizona need to know.

"To understand how pricing works in different states, we can highlight what pathologists charge in a given state and then compare those figures to what pathologists charge nationally," he said. "CPT code 88305 is, by far, the most common pathology code in the database, representing 45% to 50% of all pathology billing.

90th, 75th, 25th Percentiles

"Nationally, the 90th percentile for an 88305 professional component is $260, while the prevailing rate at the 75th percentile is $213," he noted. "Our review also provides information on what pathologists charge at the 25th and 50th percentiles.

"In my view, the ideal pathology pricing lies between the 50th and 75th percentiles," commented Tessier, who has been advising pathology practices on reimbursement issues for more than 30 years. In addition, he once worked for the **Health Care Financing Administration**, which was the forerunner to the current federal agency that pays healthcare providers, the Centers for Medicare and Medicaid Services.

"Pathologists should not charge at the 90th percentile unless they have a particular reason to do so," he advised. "The only reason to charge at that level is if you already have a high contracted rate—but that would be unusual.

"When pathologists or hospital executives compare fees for pathology practices, they're interested in determining whether the practice is within the norm for its area," he said. "Hospital and health systems want to know what the norm is, and they want to keep their group within that norm.

Ceiling for Pathology Prices

"In recent years, hospital systems have indicated that the 75th percentile is considered the prevailing rate," Tessier noted. "However, if a pathology group is charging a very low rate, such as the 25th percentile, we recommend they raise their rates gradually. We think the 75th percentile is not only a good benchmark, but also a ceiling for what a pathology practice should charge.

"It is a fact that price transparency is a trend in healthcare," he added. "That is why it is timely for all pathology groups to know what other pathologists in their area are charging.

"For example, we recently showed a client what pathologists charged in Miami and in nearby Fort Lauderdale," continued Tessier. "These numbers were then compared to pathologists' fees for the entire state of Florida.

"While the Medicare data show a rate of $213 in Florida for the 88305 professional component at the 75th percentile, the national number for global billing is $224," he said. "This shows how price sensitive global billing is for referred patients.

"In other words, there's not much difference between the professional-only

Medicare Data Show Pathology Prices, Nationally, by State, by Doctor

IT HAS ONLY BEEN THREE YEARS since the Centers for Medicare and Medicaid Services began releasing information about the prices charged by individual physicians to the public. Robert Tessier, Senior Reimbursement Consultant with HBP Services, recommends that pathologists and their practice administrators use this data to understand why other pathologists are charging in their region and state. Below is the table which shows how Tessier presents the price data for CPT 88305, including the national price and state prices for 50th, 75th and 90th percentiles.

2016 Medicare Physician Database – CPT 88305: Charge Range by State

50 States	Facility (F)			Non Facility (O)		
	50th %-tile	*75th %-tile*	*90th %-tile*	*50th %-tile*	*75th %-tile*	*90th %-tile*
National Totals	***173***	***213***	***260***	***167***	***224***	***272***
Alabama	144	160	261	123	136	150
Alaska	290	327	327	388	415	415
Arizona	98	189	235	149	255	267
Arkansas	115	128	161	106	169	191
California	170	219	262	150	195	260
Colorado	140	185	213	126	169	310
Connecticut	195	245	250	215	250	280
Delaware	171	181	181	151	171	171
Florida	199	237	260	166	201	270
Georgia	190	208	235	196	243	268
Hawaii	62	133	133	156	193	321
Idaho	124	135	135	80	168	168
Illinois	204	248	275	194	249	400
Indiana	226	242	275	211	262	374
Iowa	146	187	245	180	198	256
Kansas	200	204	260	126	235	238
Kentucky	157	198	232	175	186	200
Louisiana	100	178	200	156	184	310
Maine	147	213	213	213	213	213
Maryland	154	180	242	169	173	233
Massachusetts	147	184	199	203	216	248
Michigan	152	172	231	129	165	274
Minnesota	125	180	233	125	163	208
Mississippi	168	200	221	126	216	241
Missouri	180	193	238	150	262	271
Montana	106	122	150	139	139	206
Nebraska	153	213	213	134	147	194
Nevada	338	358	369	188	240	265
New Hampshire	223	365	366	245	245	245
New Jersey	160	192	284	225	309	432
New Mexico	130	181	261	92	93	93
New York	131	188	204	240	260	335
North Carolina	163	192	220	133	152	197
North Dakota	123	146	147	193	196	202
Ohio	187	226	240	184	211	252
Oklahoma	169	188	227	134	154	182
Oregon	113	150	165	142	184	234
Pennsylvania	142	196	232	157	240	272
Rhode Island	167	186	188	183	200	200
South Carolina	191	214	226	160	198	237
South Dakota	197	197	197	148	195	218
Tennessee	126	188	247	176	229	266
Texas	247	275	301	200	246	279
Utah	125	165	232	133	163	167
Vermont	210	211	214	172	172	213
Virginia	187	206	257	161	200	250
Washington	115	120	192	192	209	250
West Virginia	130	175	260	189	189	189
Wisconsin	254	317	336	316	319	463
Wyoming	221	301	323	401	401	401

($213) and the professional-plus-technical ($224) national rates in the Medicare database," he added.

"Of course, while these numbers are interesting, it is more relevant for pathologists to compare their rates to those of other pathologists in the same state," he said. "It is also an effective business strategy to fine-tune your fees by examining the region served by your pathology group.

"We worked with a client group in Michigan, for example, that charged an extremely low rate—$99 for the professional component of an 88305," Tessier added. "At the time, the 50th percentile in Michigan was $152 and the 75th percentile was $172.

"Our client leveraged this information to ask for higher rates from their payers, he noted. "However, the reaction from the payers, who were reimbursing at $65, was less than positive. Payers said their norm was to reimburse, on average, 50% of what is normally charged in a particular area. Because our client had set its rates so low, they were at a disadvantage when negotiating with their health insurer.

Negotiating with Payers

"This is one reason why pathologists need to know what's representative in their communities," advised Tessier. "This information helps them negotiate with third parties from a position of strength. Once this Michigan group understood that, they did not want to leave money on the table.

"With our recommendation, the group increased its fee from $99 to $150," he said. "This put them in line with the 50th percentile in Michigan. The higher rate also brought them closer to the norm compared with what other pathologists were charging in their market.

"Ultimately, it is difficult to achieve a significant rate increase," added Tessier. "The attitude among third-party payers is, 'No matter how low your rates were set, we are not going to compensate for years of neglect.'

"The payers we work with expect pathology practices to challenge their reimbursement rates and request a cost of living adjustment when contracts come up for renewal," he noted. "If groups don't do that on a regular basis, they can't expect to get a raise several years later.

"Now that this Medicare data is readily available," emphasized Tessier, "there is no reason to be unprepared for negotiating. Ideally, we recommend pathology groups set their fees close to the 75th percentile. If you're lower, you may have trouble getting a better reimbursement rate. It's that simple.

"Many factors determine what pathologists charge," Tessier explained. "One anomaly is in New Hampshire. There, the 75th percentile for an 88305 is $365, and the 90th percentile is $366. Now, why is that? This usually happens when one dominant health system charges a particularly high rate.

"In Maine—which borders New Hampshire—the 50th, 75th, and 90th percentile rates are just $147, $213, and $213, respectively," he added. "Even in Massachusetts, which has a reputation for high healthcare rates, the fees for an 88305 are $147, $184, and $199. All of those are neighboring states, yet in New Hampshire the numbers are considerably higher.

"Now look at Montana, where the prices go from $106 at the 50th percentile to $150 at the 90th percentile," he added. "Those are very conservative numbers.

"In this new era of fee transparency, it is wise for pathologists to re-examine their fees in the context of their competitors' rates," advised Tessier. "Not only does this help when negotiating contracts with payers, but it will help the pathology group with those patients who want to know prices in advance of service." TDR

—Joseph Burns

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Notable People

Respected Pathology Consultant Laurence J. Peterson Dies

In a career spanning four decades, Peterson became the go-to expert in the business of pathology

MANY PATHOLOGISTS currently leading academic pathology programs and private pathology groups got some of their best business advice from Laurence J. Peterson, CPA. For more than 30 years, Peterson was involved in the operation of both clinical laboratories and anatomic pathology groups throughout the nation.

Peterson's family reported that he died on December 25, 2017. He was the President of **Torrey Consulting Group**, Inc., based for many years in El Paso, Texas, before relocating to Surprise, Arizona, in the years before his retirement in 2005.

Laurence J. Peterson
1939-2017

As early as 1967, he was the Chief Financial Officer of **Lutheran Hospital of Maryland**, an inner city teaching hospital in Baltimore. By 1977, he was the Vice President of Finance for **Tulane University** in New Orleans, where he was responsible for developing the university's first balanced budget in almost 50 years. While at Tulane, Peterson oversaw development of systems and procedures in the University's new hospital, structured the medical faculty practice plan, established rate strategies, and negotiated.

Peterson's successes at this major academic medical center brought him to the attention of other academic institutions. Within a few years, Peterson was in high demand to help academic departments of pathology and laboratory medicine with their business and management needs.

Leader of TIPII

During the 1980s, with his consulting company now well-established, Peterson was chosen to be the President and Executive Director of **The Independent Pathology Institute, Inc.** (TIPII). This was an association of several dozen of the larger regional independent clinical lab companies still owned and operated by pathologists.

Torrey Consulting built an impressive list of clients in 46 states. During the last 20 years of his career, Peterson was particularly focused on consulting with academic and private pathology groups across the nation.

Peterson served as an advisor to medical societies in matters pertaining to physicians' compensation, third party payer reimbursement, cost containment, joint ventures and contractual arrangements. He was regularly invited to speak on these subjects at clinical lab meetings and anatomic pathology conferences. His wife Jeannie often accompanied him on his travels and had an active role in the company. TDR

IVD Sector Update

Biggest IVD Manufacturers Report Robust Third Quarter Earnings

Growth in core lab testing is modest compared to the molecular, genetic, and tissue segments

In a time of shrinking lab budgets and falling prices for lab tests in the United States, how are the larger *in vitro* diagnostic (IVD) manufacturers doing? A look at third-quarter financial reports provides useful insights as to which segments within the IVD industry are doing better than others.

In alphabetical order, here's a quick snapshot of the third-quarter earnings of several of the major IVD companies.

Abbott Laboratories

Abbott Laboratories announced Q3-2018 earnings on Oct. 17. Its diagnostics business posted revenue of $1.8 billion, which was an increase of 7.5% over revenue of $1.3 billion in the same quarter the previous year. During third quarter, these diagnostics segments grew as follows: core laboratory sales up by 6% to $1.19 billion; molecular sales up by 5% to $121 million; and point-of-care sales up by 4% to $136 million.

Danaher Corporation

Danaher Corporation has acquired a string of IVD companies in recent years and now is one of the major players in diagnostics. In its Q3-2018 earnings report issued on Oct. 17, it said that core diagnostics revenue grew by 3.5%, to $1.5 billion.

Among the divisions, revenue at **Beckman Coulter** grew "in the low single digits," **Radiometer** and **Leica Biosystems** were both up in "high-single digits," and **Cepheid** "delivered double-digit core revenue growth."

Roche Diagnostics

On Oct. 17, **Roche Holding AG** reported that, during Q3-2018, revenue at **Roche Diagnostics** grew 6% over Q3-2017, to US$3.1 billion, compared to US$3.0 billion in Q3-2017. Company officials said that business revenues at the centralized and point-of-care solutions grew by 8%; molecular diagnostics increased by 6%; and, tissue diagnostics went up by 9%.

Siemens Healthineers AG

Earlier this year, **Siemens AG** spun off its imaging and diagnostics businesses into a new company called **Siemens Healthineers AG**. The company's initial public offering raised $5.2 billion on March 15.

Siemens Healthineers is scheduled to report its third-quarter 2018 earnings on Nov. 5. In its second-quarter 2018 earnings, it said that diagnostics revenue for that period was $1.2 billion. This was a decline of 4% from the $1.05 billion revenue total for the same quarter in 2017.

It is no surprise that core lab revenue at these companies is in the low single digits. These tests are mostly automated and run at high-volumes. Growth rates are much stronger in point-of-care, molecular, and genetic testing segments, due to expansion of precision medicine services. TDR

Quest Acquires Two Labs, Two Other Health Firms

Within days, Quest Diagnostics bought PhenoPath, ReproSource, and lab business of Oxford Immunotec

CEO SUMMARY: In the span of four days in September, Quest Diagnostics agreed to buy two lab companies and the lab testing service line of a third firm. In August, it purchased wellness company Provant Health, which had earlier filed a bankruptcy action. Each of these transactions helps Quest concentrate more on proprietary products and market share. The real gem in this buying spree is PhenoPath, the specialty pathology practice and reference laboratory that is widely-respected for its expertise.

WITH ITS PURCHASE OF TWO LAB COMPANIES, **Quest Diagnostics Inc.** is continuing the trend of consolidation in the clinical laboratory marketplace. It also acquired two other healthcare companies.

On Sept. 27, Quest Diagnostics purchased **PhenoPath, PLLC**, in Seattle. Days earlier, it announced the acquisitions of **ReproSource** in Woburn, Mass. (on Sept. 24) and the lab services business of **Oxford Immunotec Global PLC**, a company in Oxford, England (on Sept. 25). At the end of August, Quest also acquired a bankrupt wellness company called **Provant Health**, a company in East Greenwich, R.I.

Of these four acquisitions, PhenoPath is probably the best-known within the clinical lab profession. Founded by pathologist Allen Gown, MD, in 1998, it is a physician-owned specialty pathology practice and reference laboratory in Seattle.

PhenoPath offers diagnostic and contract research services to pathology and oncology practices, hospitals, biopharmaceutical companies, and research institutions in the United States, Canada, and around the world, the company said on its website. It offers immunohistochemistry, flow cytometry, fluorescence *in situ* hybridization tests, molecular assays, and chromosome analysis, it added.

The PhenoPath acquisition is particularly important because this AP provider has a long and distinguished history in the Pacific Northwest. Under terms of the deal, PhenoPath will become part of **AmeriPath**, a division of Quest that focuses on anatomic pathology.

Reason for PhenoPath's Sale

In a letter to its customers, PhenoPath said it agreed to become part of AmeriPath, because the physicians at PhenoPath wanted to continue to provide patients with "the most advanced services."

In the letter, PhenoPath CEO Tim Rich and Quest Senior Vice President, Commercial, Everett Cunningham, said that AmeriPath and PhenoPath will offer, "an expanded network of renowned pathologists both at the PhenoPath facility in Seattle and the existing Quest Diagnostics operation in nearby Portland,

Ore., coupled with Quest's national pathology community."

The other lab company Quest acquired was ReproSource, a specialty fertility services company in Woburn, Mass. ReproSource offers diagnostic tests to women seeking fertility services, including genetic-based ovarian health and recurrent pregnancy loss assessments, Quest said. In an effort to bolster its offerings in women's health and reproductive services, Quest said it will offer ReproSource's services nationwide.

Quest did not disclose terms for any of the deals it announced in September.

The third acquisition Quest made involved the lab services business of Oxford Immunotec Global PLC, a company in Oxford, England, that Quest described as being a "global, high-growth diagnostics company."

The company offers tuberculosis and tick-borne disease testing services at laboratories in Memphis, Tenn., and in Norwood, Mass. Under the terms of the deal, Oxford Immunotec will sell its TB test kits to Quest under a long-term supply agreement. The two companies hope to see an increase in testing for TB in the United States.

Company in Bankruptcy

At the end of August, Quest also acquired a bankrupt wellness company called Provant Health, of East Greenwich, R.I., that claims to be the largest publicly-traded, health and well-being provider in the United States.

Under an asset purchase agreement, Quest will acquire substantially all of Provant Health's assets and will continue to offer the company's wellness services to corporate and other clients. If the bankruptcy court agrees with the terms of the transaction, it is expected to close in October.

Quest's acquisitions of PhenoPath, ReproSource and proprietary tests from Oxford Immunotech show that consolidation and the concentration of market share continues in both the *in vitro* diagnostics (IVD) and clinical lab sectors, as companies buy up smaller firms. TDR

—Joseph Burns

Quest Purchased MedXM in January

IN THE FIRST QUARTER OF THIS YEAR, Quest Diagnostics acquired **Mobile Medical Examination Service (MedXM)**, a company in Santa Ana, Calif., that provides home-based health risk assessments.

This acquisition and Quest's emphasis on closing gaps in care is significant as the billion-dollar clinical lab company works to position itself as a resource and a partner to health insurers delivering population health services outside of hospitals and other traditional sites of care.

MedXM has a network of more than 1,700 medical professionals operating nationwide who provide what Quest described as "a high-touch personalized approach that engages members, often at home, in assessing their health and risks." These are patients who have been hospitalized or who may need to be hospitalized but are being cared for in lower-cost settings.

"Health plans use data from assessments to coordinate with physicians to ensure they take pre-emptive actions to reduce identified risks," Quest said about MedXM earlier this year. "Data from the assessments may also aid risk scoring and quality tracking of managed populations."

At the time, Quest touted the ability of MedXM to expand its ability to close gaps in care, saying, "The acquisition will expand Quest's scale and reach in the mobile and home segment and bolster its overall capabilities in extended care." With the MedXM deal, Quest said it would "focus on connecting with patients in homes, retail stores, and other convenient settings."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Efforts to enroll one million veterans in a program to determine how genetic variations affect health is moving swiftly. Current enrollment is 700,000 veterans and the one million goal is expected to be reached by 2021. In 2011, the federal **Department of Veterans Affairs** instituted the VA Million Veterans Program (MVP).

MORE ON: *Million Vets*

Recently the VA extended a contract with P**ersonalis, Inc.**, to sequence an additional 34,000 whole human genomes as part of the VA Million Veterans Program. Personalis already had contracts with the VA to sequence 80,000 human genomes.

AVERAGE AGE OF MED TECHS IS NOW YOUNGER

One trend that shows up in the just-released ASCP 2017 Wage Survey is that the average age of medical technologists (MTs) and other lab scientists is becoming younger. In a press release issued by the **American Society for Clinical Pathology** (ASCP), it stated, "The overall medical laboratory workforce across the United States is gradually getting younger as increased numbers of longtime employees in the profession are retiring." The data behind this finding demonstrates that the ongoing wave of baby boomer MT retirements is large enough to cause the average age of lab scientists in many lab organizations to trend younger. This reverses the trend seen through the 1990s, 2000s, and 2010s. Each year, the ASCP conducts this survey and the full results of the current survey are posted online at the website of the *American Journal of Clinical Pathology*. This year's survey gathered data from almost 15,000 clinical laboratory professionals.

TRANSITIONS

- Khosrow Shotorbani is the first Executive Director of the **Project Santa Fe Foundation**, recently formed by the pathology chairs of four health system laboratories. Shotorbani's previous positions were at **Tricore Reference Laboratories**, and **ARUP Laboratories**.
- **Assuragen, Inc.**, of Austin, Texas, appointed Tom Copa as its new Senior Vice President of Commercial Operations. Copa formerly held positions at **Luminex Corporation**, **Cardinal Health**, **Baxter**, and **Allegiance Healthcare**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 12, 2018.