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Reynolds Salerno, PhD

CDC's Division of Lab Services Is Resource for Clinical Labs

CLIA NEWS, COVID, MONKEYPOX

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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

Clinical Laboratory News from North of the Border

In mid-October, Canada's largest national conference for diagnostics leaders took place in Toronto. It was their first gathering since the onset of the pandemic and much is happening with healthcare and medical laboratories in our northern neighbor. The Dark Report was there to identify innovative developments that might be useful to our clients and regular readers.

Presentations emphasized three themes. One important theme centered around new diagnostic technologies and how early-adopter labs in Canada were using them to improve patient care. The second theme involved reports from most of the nation's larger provinces as to how labs in those provinces were dealing with the inadequate supply of skilled laboratory professionals, the continuing supply chain disruptions, and the way inflation is driving up the cost of both supplies and labor. The third theme dealt with public policy initiatives that involve diagnostics and might open doors for Canadian labs to add more value to physicians, patients, and provincial health authorities.

This all sounds familiar to labs on this side of the border, right? But there is an intriguing difference. Due in part to Canada's single payer health system, since the 1990s, most provincial health authorities have diligently worked to regionalize, integrate, and standardize the different laboratory sites throughout their province. The common goal is to squeeze out unnecessary costs and one way to do that is to centralize testing into ever-larger core labs where possible. Another shared strategy is to harmonize lab analyzers, test menus, and laboratory information systems (LIS) wherever possible within a province.

The best illustration of this trend is happening in Quebec. In a major project named "OPTILAB," the province is organizing its 123 laboratories into 12 clusters. This initiative launched in 2013 and is probably the single largest clinical laboratory regionalization project in the world. Each cluster is tasked to move toward common instrumentation, test method, and reference ranges across all lab sites. Probably the most ambitious goal within OPTILAB is the adoption of a single LIS across all labs in the province. During the next six months, at least four clusters will go live with the same LIS product, provided by a certain healthcare information company based in Wisconsin. TDR

U.S. Hospitals Will Lose Billions of Dollars in 2022

For year to date, many hospitals report sizeable losses in both patient revenue and investments

CEO SUMMARY: Hospitals and health systems in most regions of the United States are reporting substantial losses, both in patient care and in the value of their investment portfolios. This is inauspicious for the clinical laboratories operated by these hospitals. Hospital-based managers can expect more pressure to cut lab costs continually, even as they must simultaneously deal with steady increases in the cost of labor their hospital lab requires to service the needs of inpatients.

by Robert L. Michel

RECENT REPORTS ON THE STATE OF HOSPITAL FINANCES in the United States through August 2022 paint a troubling picture for this sector of the healthcare system. Experts say that more than half of the nation's hospitals are running in the red amid declining patient volumes and inflation-fueled increases in supply prices and salaries.

This is bad news for the managers and pathologists working in the clinical laboratories of hospitals and integrated health systems because this is the third consecutive year of deteriorating finances for the hospital industry.

Across the board, hospitals are squeezing costs wherever possible. For many hospital-based labs, 2022 is the third consecutive year that administrators asked their clinical labs to cut spending below the original budget amounts for the year. The financial picture for hospitals in 2023 is expected to be equally gloomy.

It is not an exaggeration to characterize hospital losses as a tsunami of red ink. There are few national news stories about the magnitude of financial loses at hospitals. One reason this is true is because healthcare policymakers and hospital CEOs do not want negative news coverage that might erode the confidence patients have in the quality of care provided by their local hospital.

Despite the fact that there is not much local and national news coverage about the decline in hospital revenues and the deterioration in their financial condition, industry consultants and Wall Street firms

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are publishing reports that highlight these critical financial issues.

For example, in its "National Hospital Flash Report" for August 2022, a report prepared by **Kaufman Hall** for the **American Hospital Association** (AHA), the authors wrote this summary:

> *U.S. hospitals and health systems are experiencing some of the worst margins since the beginning of the pandemic, and 2022 continues to be on pace to be the worst year of the pandemic in terms of financial performance ... Hospitals can no longer count on supplemental [COVID-19] federal funding to buffer these mounting losses, as they did in previous pandemic years. The situation is so dire that on August 16* ***Fitch Ratings*** *revised its sector outlook for U.S. not-for-profit hospitals and health systems to 'deteriorating.'*

Chicago-based Kaufman Hall did not provide an estimate of the collective losses at the nation's hospitals in either its August or September 2022 reports. However, the American Hospital Association published a report in early 2021 titled "Hospitals Face Continued Financial Challenges One Year into the COVID-19 Pandemic." In this report, AHA wrote:

> *In 2020, hospitals were projected to lose an estimated $323 billion, leaving nearly half of America's hospitals and health systems with negative operating margins by the end of 2020.*

Magnitude of Finanical Woes

Simple math illustrates the magnitude of financial losses at the nation's hospitals during 2020. Published government data shows the total healthcare spend in the United States as $4.1 trillion. Of that, $1.3 trillion was spent on hospital care.

Therefore, AHA's projection of a collective loss in 2020 of $323 billion—a third of a trillion dollars—represents an amount equal to 25% of collective hospital revenue during that year! Comparable data for 2021 was not found, but it is reasonable to assume that the collective losses at the nation's hospitals that year were substantial and totaled in the hundreds of billions of dollars.

Across the nation, there are some reports of the financial performance of hospitals. Earlier this month, the **Washington State Hospital Association** published the results of its second financial survey of state hospitals during 2022.

The Seattle Times wrote, "Results of the association's first survey, released in July, showed Washington hospitals suffered a net loss of about $929 million in the first three months of 2022. That number has increased to nearly $1.8 billion for the first six months of the year, meaning hospitals lost another $820 million in the second quarter of 2022."

There are about 91 acute care hospitals in Washington. Dividing those 91 hospitals into the $1.8 billion loss for the first six months of 2020 reveals that the average loss for a hospital in Washington State during that time was almost $20 million.

$250 Million Loss for YTD

Also in the same story about hospital finances, *The Seattle Times* wrote "**MultiCare** [with eight hospitals], based in Tacoma, has experienced more than a $250 million loss so far this year, including a $22 million loss in August."

It is a similar story at **Kaiser Permanente**. In August, *Healthcare Dive* noted that "Kaiser Permanente reported a net loss of $1.3 billion in the second quarter, compared to net income of $3 billion in the same period a year ago, stung by investment market conditions."

In the Midwest, the problems of finances and staff at one Michigan integrated delivery network was highlighted in a report published by *Fierce Healthcare*. Reporter Dave Muoio wrote:

> *Mike Slubowski, president and CEO of 88-hospital* ***Trinity Health****, said his organization has nearly 3,900 vacant*

Statistics for Hospital Woes in 2022 Illustrate the Wide Spectrum of Problems and Challenges

THIRD QUARTER FINANCIAL REPORTS WILL SOON BE RELEASED by hospitals and health systems that hold debt sold to the public. It is expected that more than 50% of the nation's hospitals will report losses during 2022.

In September, consulting firm Kaufman Hall issued a report it prepared for the American Hospital Association. It was titled "The Current State of Hospital Finances: Fall 2022 Update."

Hospital Industry Finances

This report included information that is helpful for those lab administrators and pathologists serving in hospital laboratories who want to better understand how current market forces are eroding hospital finances. Kaufman Hall wrote:

- "More than half of hospitals are projected to have negative margins through 2022. Projections for the remainder of the year demonstrate an increase in hospitals with negative margins relative to prepandemic levels, to 53%.
- "Expenses are significantly elevated from prepandemic levels. Expenses are projected to increase throughout the rest of 2022, leading to an increase of nearly $135 billion over 2021 levels. Labor expenses are projected to increase by $86 billion, while non-labor expenses are projected to increase by $49 billion. *[Editor's note: Assume hospital revenue of $1.5 trillion during 2022. Kaufman Hall's projection of increased costs of labor and non-labor during 2022 is $135 billion. That is 9% of the $1.5 trillion in projected 2022 hospital revenue.*]
- "Hospitals also are facing a host of other related challenges, including workforce shortages, supply disruptions, and rising expenses.
- "Projections for the entirety of 2022 indicate an increase in hospitals with negative margins, to 53%. Under a pessimistic scenario for 2022, 68% of hospitals would have negative margins."

Last week, *Medical Economics* published a story about deteriorating finances of hospitals that showed the magnitude of certain trends. It noted that inpatient orthopedics volume for osteoarthritis care (including total knee replacement patients) is down 80% for 2022 YTD compared to the same period in 2019.

In the same story, Steve Lefar, chief strategy officer at **Strata**, said, "The StrataSphere data shows the U.S. health care industry is comprised of 'haves and have nots,' with far too many on the 'have not' side. ... Inpatient volumes have not yet returned to pre-COVID levels. Cases are moving away from profitable procedures, and outpatient volumes have only made slight gains since 2019. Health systems, regulators, and industry analysts must rethink how they model a variety of future state scenarios."

Financial Struggles Ahead

Over the past 15 years, Wall Street firms have published reports and studies that documented financial strength was deteriorating at an increasing number of hospitals and integrated delivery networks (IDN). *(See TDR, "New Report Says Half Nation's Hospitals Have Financial Woes," May 27, 2008.)*

During this same 15 years, a majority of mergers involving hospitals and integrated delivery networks (IDNs) happened because one party to the merger could no longer operate independently due to years of financial losses. The data presented above indicate that more hospital consolidation may happen soon.

registered nurse positions as well as a 14% clinical support staff vacancy rate.

The staff shortages "are like nothing we've ever seen before," he said, and have forced Trinity to take 12% of its beds, 5% of its operating rooms, and 13% of its emergency departments offline.

"We have some locations with as high as 20% to 25% of their beds offline, and half of their operating rooms and diagnostic services offline due to nurse staffing shortages," he said. "We're doing all we can including innovating how we deliver patient care, but it isn't enough. Hospitals, long-term care facilities, home care, and physician practices lack the resources needed to solve the healthcare workforce crisis ourselves."

Three Biggest Trends Today

Meanwhile, there is plenty of news coverage about the three biggest trends hammering hospitals, physician clinics, and ancillary providers, including clinical laboratories. Those trends are:

- Ongoing pressures to continually cut costs by substantial amounts.
- Urgent need to recruit, hire, and retain adequate staff in all skill positions.
- Inflation rates that are the highest in 40 years and show no signs of easing.

Inflation is the new and unwelcome contributor to the higher costs of clinical lab and pathology instruments, tests, and consumables—along with fueling a steady increase in staff salaries.

This intelligence briefing provides lab managers, pathologists, and their practice administrators with a more detailed picture about the scope and scale of the erosion of hospital finances now happening throughout the United States.

One consequence of these trends will be an increase in the number of hospitals that decide to sell their lab outreach businesses to bolster their cash reserve. **TDR**

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Nurse Pay Skyrockets, Operating Rooms Closed

JUST AS HOSPITAL LABS ACROSS THE UNITED STATES cannot hire and retain adequate numbers of clinical lab scientists and staff, hospitals have similar staffing problems, particularly with nurses.

Timely, accurate data on the rate of pay increases for lab scientists is not easily found. However, there are news stories documenting increases in compensation paid to nurses.

In covering how the money hospitals spend on salaries is rising, *Kaiser Health News* (*KHN*) recently wrote about the hospital staffing shortage. It included one example that shows how much labor costs have risen during 2022.

Kaiser Health News quoted Brad Ludford, CFO at **Bozeman Health** in Bozeman, Mont. Ludford explained how the the system "went from spending less than $100,000 a month on short-term workers before the pandemic to $1.2 million a week last fall."

Currently, Bozeman Health spends $1.4 million per month on short-term workers. He said total labor costs are now $20 million per month, an increase of about 12% from the same time last year. The health system has 487 open positions for "essential workers."

Bozeman Health President and CEO John Hill told *KHN* that, prior to eliminating staff positions, his organization took the following steps to cut costs:

- All out-of-state business travel ceased.
- Executive compensation was cut and workloads readjusted.
- Attempts were made to convert hospital contract workers into full-time employees.
- A minimum wage increase was offered to improve retention of existing staff members.

Legal Update

Ex-Theranos CEO Elizabeth Holmes Awaits Ruling on New Trial Request

KEEPING WITH THE UNEXPECTED AND ODD CIRCUMSTANCES SURROUNDING **THERANOS**, a federal judge heard arguments on Oct. 17 about whether convicted company founder Elizabeth Holmes' should get a new trial.

That hearing stemmed from the government's star witness in Holmes' 2021 trial—a pathologist—visiting her home in August to speak with the disgraced former Theranos CEO.

As of press time, Judge Edward Davila at **U.S. District Court for the Northern District of California** had not ruled on the motion for a new trial.

While this latest twist was dramatic, of greater interest to lab managers and pathologists is how the latest court filings shed even more light on the testimony of the witness, former Theranos Lab Director and pathologist Adam Rosendorff, MD.

THE DARK REPORT checked with attorney Matthew Murer, chair of the national healthcare practice at law firm **Polsinelli** in Chicago, about the new court documents. Murer concluded that the filings reiterated the responsibilities of lab directors under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Liability from Flawed Testing

Murer further noted that Rosendorff recognized liabilities in how Theranos conducted flawed diagnostic blood testing with its Edison machine.

"Theranos failed to properly conduct proficiency testing because they couldn't get accurate results on their standard testing," Murer recalled. "So, here's the CLIA laboratory director telling the jury that he knew Theranos wasn't following the proper protocol for proficiency testing, and it really was a way of cheating."

Holmes was convicted in January on four counts of defrauding Theranos investors and conspiracy to commit wire fraud. *(See TDR, "Jury Finds Elizabeth Holmes Guilty in Four of 11 Criminal Counts," Jan. 10, 2022.)* Her sentencing was delayed until Nov. 18 due to her motion for a new trial.

Visit to Holmes' Residence

According to a court document filed by Holmes' attorneys, on Aug. 8, Rosendorff visited the residence of Holmes and her partner, Williams Evans, in Woodside, Calif. Rosendorff asked to speak to Holmes, a request that Evans declined.

"Dr. Rosendorff explained that he wanted to speak to Ms. Holmes because it would be 'healing for both himself and Elizabeth to talk,'" the filing stated, which was referencing Evans' recollection of the conversation.

Evans alleged that Rosendorff stated he tried to answer questions honestly in his testimony during Holmes' 2021 trial, but that "the government made things sound worse than they were," and that employees at Theranos were "working so hard to do something good and meaningful," according to the court document.

Further, Evans alleged that Rosendorff "stated that 'he fe[lt] guilty' and that he 'felt like he had done something wrong,' apparently in connection with his testimony in Ms. Holmes' case," the filing said. "He stated that these issues were 'weighing on him' and that 'he was having trouble sleeping.'"

Based on Rosendorff's alleged statements to Evans, Holmes' attorney sought a new trial or at least an evidentiary hear-

ing. The motion for a new trial argued that Rosendorff's words raised questions about how prosecutors presented evidence during the trial and cast doubt on Holmes' guilty verdict.

Truthful Testimony

However, on Sept. 15, Rosendorff signed an affidavit confirming that his testimony was accurate in both Holmes' trial and that of former Theranos Chief Operating Officer Ramesh "Sunny" Balwani.

Asked by Judge Davila during the Oct. 17 evidentiary hearing whether he testified truthfully, Rosendorff confirmed he had. But he also expressed remorse over how Holmes and Evans' one-year-old child would be without a mother if Holmes receives prison time for her convictions, *The Wall Street Journal* reported, noting that Holmes "appeared at court visibly pregnant" during the hearing.

Murer also suspected the discrepancy between what Rosendorff said at Holmes' residence and what he stated in his affidavit comes down to how Theranos was portrayed during the trial.

"The phrase that comes up in a lot of the filings is, 'We were all working very hard at trying to make this technology work,'" Murer noted. "What the government said is, 'That may have been everyone's intent at Theranos, but Holmes knew that the technology didn't work and then lied to the investors to get them to invest.'"

Subpoena to Obtain Emails

Before the hearing, Holmes' legal team attempted to subpoena Rosendorff's emails about his past testimony. Rosendorff's attorneys filed a motion in court to quash the subpoena, which Davila agreed to do after finding the subpoena to be excessive, the *San Jose Mercury News* reported.

Murer also wanted to inform other CLIA lab directors about insightful information in Rosendorff's testimony that has not been publicly discussed. In its opposition to Holmes' motion for a new trial, the government brought up further noteworthy details about what Rosendorff witnessed at Theranos.

"Once Theranos started offering tests to patients, Dr. Rosendorff continued to observe accuracy problems with one Theranos assay after another," the government stated, paraphrasing trial testimony.

"In mid-2014, Theranos' HCG assay—used to monitor pregnancy status—was performing so poorly in patient testing that Dr. Rosendorff ordered it moved to standard commercial analyzers, forbidding the lab from running it on the Edison device." Doing so illustrates the steps laboratory directors must take under CLIA to ensure proper testing.

'Not Getting Good Results'

"That's a good example of how proactive CLIA lab directors need to be," Murer said. "Rosendorff knew that these Edison machines weren't getting good results, so he ordered all the testing to go over to commercial analyzers to make sure the tests were getting accurate results. That's a smart move for a lab director."

A surprising revelation in court documents concerned when Rosendorff quit Theranos in 2014. "Around the time of his departure, Dr. Rosendorff was exploring the possibility of bringing a federal whistleblower lawsuit against Theranos, in order to 'right the wrongs, basically, to alert the public of what was going on at Theranos,'" the government stated.

Despite the hoopla of the Holmes trial, Rosendorff's actions while at Theranos were consistent with CLIA requirements—something CLIA lab directors elsewhere should note, Murer explained.

"Dr. Rosendorff decided to leave Theranos due to things he witnessed there," Murer concluded. "He testified that he felt it was a question of his integrity as a physician to remain at Theranos and to continue endorsing results that he didn't have faith in. He was uncomfortable with what was happening in the company, and he felt pressured to vouch for results in which he was not confident." TDR

IVD Update

Reports Say Qiagen and Bio-Rad Discussing Potential IVD Merger

More consolidation in the *in vitro* diagnostics (IVD) market may soon happen. **Bio-Rad Laboratories** and **Qiagen** are reportedly in merger discussions. *The Wall Street Journal*, which broke the story on Oct. 10, tabbed the potential deal as being worth $10 billion should it go through.

Both companies have a global presence and make most of their sales outside the U.S., said Bruce Carlson, Senior Vice President at **Kalorama Information**, part of the **Science and Medicine Group** in Arlington, Va.

"If the deal occurs, there could be a compounding of strengths in infectious disease testing, which is the fastest growing and largest area of IVD right now," Carlson commented. "Qiagen is strong in tuberculosis testing and has an HPV [human papillomavirus] business. Bio-Rad offers a range of microbiology tests and also does quality control and blood banking."

Representatives for both IVD companies did not return requests for comment from The Dark Report.

Increased Market Share

Bio-Rad in Hercules, Calif., was tied for ninth place among the biggest global IVD companies based on its 2021 earnings of $2.9 billion, according to analysis from The Dark Report. *(See TDR, "2021 Rankings of the World's Top 12 IVD Companies," Aug. 29, 2022.)*

Qiagen, based in Germany, barely missed placing on our IVD company list with revenues of $2.3 billion in 2021. Revenues for both companies include life science and research laboratory products, in addition to IVD, Carlson said.

A combined company would likely increase its ranking on the top IVD list.

"A deal between Qiagen and Bio-Rad would be the latest tie-up in the medical diagnostics market, which has grown as the pandemic increased demand for medical testing," *The Wall Street Journal* reported.

The continued consolidation of the IVD market points to fewer large companies holding more market share. Most recently, at the end of last year, Quidel acquired **Ortho Clinical Diagnostics** in a deal worth $6 billion. *(See TDR, "Ortho Clinical Diagnostics to Be Acquired by Quidel," Jan. 10, 2022.)*

"As IVD companies look at this potential merger and others that have occurred—such as **Quidel** and Ortho and **SD Biosensor** and **Meridian Bioscience**—it might beget other mergers or at least more talks," Carlson observed. "No one wants to be left out as a smaller distributor."

Changes for Lab Customers

Depending on the specific details of the potential merger, clinical laboratories that use products from either Qiagen or Bio-Rad could face changes in technical support services and sales.

Carlson also saw other aspects for customers. "Long term this deal could be potentially beneficial from a standpoint of laboratories seeking to reduce the amount of purchase processes, vendor contracts, and service agreements," he said.

Lab managers and pathologists should monitor news about the potential deal between Qiagen and Bio-Rad, as its implications may be far reaching for the IVD industry as firms try to expand market share and drum up post-pandemic business. TDR

NEWSMAKER INTERVIEW

Reynolds Salerno PhD, CDC

CDC's Div. of Laboratory Services Talks COVID-19, CLIA, and More

"We need to envision a laboratory system that crosses public health and private sector boundaries and learns how to collaborate with one another."
—Reynolds Salerno, PhD

CEO SUMMARY: In this exclusive interview, the Director of the Division of Laboratory Systems at the CDC offers insightful comments about the federal agency's response to the SARS-CoV-2 pandemic, what went right during public health efforts, and lessons that were learned. He also discusses how labs have dealt with the recent monkeypox outbreak and what significant changes may be in store for the Clinical Laboratory Improvement Amendments of 1988.

EDITOR'S NOTE: Reynolds Salerno, PhD, had a front row view into the federal government's response, both to the SARS-CoV-2 pandemic and the recent monkeypox outbreak. As Director of the Division of Laboratory Systems (DLS) at the **U.S. Centers for Disease Control and Prevention** (CDC), Salerno had an instrumental role in how diagnostic testing was provided during recent public health emergencies.

Salerno explains why the clinical laboratory and public health worlds will come together and how that relationship has been strained in the past. He also discusses possible revisions to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), previewing Clinical Laboratory Improvement Advisory Committee (CLIAC) recommendations that he considers could be significant reforms to CLIA.

EDITOR: Can you explain the current structure of the Division of Laboratory Systems (DLS) within the CDC?

SALERNO: The DLS reports to the CDC's **Center for Surveillance Epidemiology and Laboratory Services**. And that center's director reports up to CDC Director, Dr. Rochelle Walensky.

EDITOR: What role does DLS have within CMS as it relates to CLIA?

SALERNO: Implementation of the CLIA program involves three federal agencies, which I often call the tri-agency. It includes the **Food and Drug Administration** [FDA], the **Centers for Medicare and Medicaid Services** [CMS], and the CDC. The FDA and CMS have regulatory oversight responsibilities for CLIA. For example, FDA authorizes diagnostic tests for use on people and categorizes tests based on their complexity. CMS inspects and enforces regulatory compliance that can result in laboratories being shut down for not operating according to the CLIA rules and regulations.

EDITOR: How do the CDC and DLS fit into the CLIA program?

SALERNO: The CDC and our division do not have the same type of regulatory oversight role in CLIA as the FDA and CMS. We at CDC cannot enforce the CLIA regulations by penalizing laboratories. However, our role is unique. I like to describe it as we sit between the regulators [FDA and CMS] on one side and the regulated community [clinical laboratories] on the other side. We are responsible for outreach, communication, and engagement with the clinical laboratory community. Our responsibility is to explain the rules, regulations, and standards as best we can to that community. We also have the important role of understanding the challenges that the laboratory community has with the CLIA regulations and communicating that back to the regulators to say, "We need to address this or that part of the regulations."

EDITOR: Despite DLS not having the power to enforce the CLIA regulations, you do have influence over regulatory development, correct?

SALERNO: Yes. We are part of the CLIA regulatory development process. The CLIA technical regulations and standards are jointly developed by CDC and CMS, and jointly signed by the CDC director and the CMS administrator.

EDITOR: What is your role in relation to the **Clinical Laboratory Improvement Advisory Committee** (CLIAC) and laboratory training?

SALERNO: The CDC manages CLIAC, which is the federal advisory committee for CLIA. On behalf of the tri-agency, we also develop and distribute technical guidance and information. DLS does a tremendous amount of training course development. We develop tools and information guides that we make freely available to the community to help them maintain compliance with CLIA. We also monitor CLIA's proficiency testing program.

EDITOR: Let's switch gears and talk about the COVID-19 pandemic. Over the past two-and-a-half years, how did DLS respond to the pandemic? And as you look back on it now, what success stories will guide you in the future with other public health emergencies?

SALERNO: I'd like to first look back at the Zika outbreak of 2016 to provide some context. Our division—even though we had the same role in CLIA that I just described to you—had basically no role in the response to the Zika outbreak. And one thing that happened during the Zika outbreak was that some of the Southern states that were most affected by Zika were overwhelmed by the demand for testing. The public health laboratories could not keep up with the demand. The CDC struggled because we did not have formal relationships with commercial laboratory companies that could help us do what we now call surge testing. We struggled to get immediate testing support from the private sector during the Zika response because we lacked those relationships.

EDITOR: How did this experience change things within the CDC and DLS?

SALERNO: After Zika, DLS recognized that it would be a benefit if the CDC and DLS could leverage their broad relationship with the clinical laboratory community to strengthen future public health responses. One of the first things we did was establish a memorandum of understanding [MOU] with the **American Clinical Laboratory Association** [ALCA], as well as the **Association of Public Health Laboratories** and the **Council for State and Territory Epidemiologists**. The memorandum signed in 2018, discussed how all parties could better prepare for surge laboratory testing when diagnostic testing, during a response, cannot be handled solely by the public health laboratories.

EDITOR: What improvements resulted from this memorandum?

SALERNO: First of all, the MOU helped us to formalize important relationships with the ACLA and the major commercial laboratories. Second, in 2019, the parties came together for a day-long tabletop exercise. By no means were all the kinks worked out for surge testing, but because of the relationships that we established, our division was able to engage with those organizations early in January 2020 when COVID-19 started surfacing. All we could do at that point was provide them with information. But just having those relationships put us in a position to begin conducting weekly and even daily calls with ACLA members very early in the national response. We are confident that outreach and communication from the CDC helped that community feel as if they were more engaged in the public health response than they'd ever been before.

EDITOR: What results did clinical laboratories see from that new engagement?

SALERNO: There were many examples. One in particular proved very effective for engaging with the laboratory community. DLS began distributing messages through what we call the Laboratory Outreach and Communication System, or LOCS. Those messages initially went to about 500 clinical laboratories that we had email addresses for, but that LOCS system grew during the pandemic to a distribution list of over 110,000 clinical laboratories across the country. LOCS became an important tool that we used—and we continue to

use—to communicate information about various preparedness and response topics to the clinical laboratory community.

EDITOR: Were there other successes?

SALERNO: DLS also started holding what were originally called Clinical Lab COVID-19 Response Calls. They're now called LOCS Calls. Initially they were every week, then every other week, and now they are held on the third Monday of each month at 3 p.m. EST. For those calls, we feature experts from CDC, FDA, and CMS, along with many other experts.

EDITOR: What were the topics of LOCS Calls initially?

SALERNO: It was an opportunity to bring the laboratory community together to discuss the latest guidance, to talk about the latest research, and to explain what we knew and what we didn't know. The calls were well attended. At some points, we had 3,000 participants every single week. Even today, when there's less urgency around public health response, between 700 and 1,000 people continue participating in each of these LOCS Calls.

EDITOR: Much CDC guidance also came out during the pandemic. Was the DLS involved with that?

SALERNO: Yes, DLS took responsibility for the majority of testing guidance that the CDC posted on its website. We developed the technical content and ensured it was approved by the subject matter experts at the CDC who may have been outside our division. We advocated that the CDC issue timely guidance, in as clear language as possible, to make this information available to the clinical laboratory and testing community.

EDITOR: How did DLS provide additional services to clinical labs?

SALERNO: One thing we were happy about was that the first guidance page that we launched in March 2020 focused on biosafety for those clinical laboratories that would be receiving testing specimens for SARS-CoV-2.

EDITOR: Was this a first for the CDC and DLS?

SALERNO: Yes. This type of biosafety guidance was not previously available. That was a problem in previous responses, especially during the Ebola outbreak in 2014. The laboratory community has criticized CDC for not providing guidance to clinical laboratories during the Ebola crisis. Many clinical laboratories were apprehensive about the risks of handling these specimens. By comparison, we received a lot of positive feedback from the community about our biosafety guidance during COVID-19, especially that it was released as early as it was. Even though it went through numerous iterations and revisions as we learned more about COVID-19, the guidance helped the clinical laboratory community prepare for handling the specimens and performing the SARS-CoV-2 testing that they were asked to do.

EDITOR: What was one useful lesson that you learned from the COVID-19 response?

SALERNO: We believe DLS made many positive contributions during the pandemic. Further, it's clear that the U.S. government and even the CDC has learned valuable lessons. We need to develop new systems and approaches to do better the next time a novel infectious agent appears.

EDITOR: You are upbeat about the learning curve at DLS and how it contributed during the pandemic.

SALERNO: One thing I value about my background in clinical laboratory quality is that the name of the game is "continual improvement." I think that's where we as an agency are as well. Given that this was a completely unprecedented historical event, DLS did many things well. Of course, there are things that didn't go as well as they should have. In terms of what our division can do better, we learned that—although we had this relationship with the ACLA and some of the largest commercial laboratories—we didn't have as deep a relationship with the broader clinical laboratory community as we should have.

EDITOR: Can you explain that further?

SALERNO: If we look at the academic medical centers and the major hospital laboratories—which provided incredible service to patients during COVID-19—DLS was able to develop relationships with some of those laboratories during the pandemic, but we didn't have those at the outset of the pandemic. Initially, we thought we were in good shape because we had relationships with **Labcorp** and **Quest Diagnostics**. But that wasn't nearly enough. The deeper we went into the pandemic, both the CDC and DLS recognized the need for more extensive relationships with the broader clinical laboratory community that could be leveraged during public health responses. This is different thinking than we had in late 2019.

EDITOR: During the swine flu outbreak in 2009, the advances in PCR testing were such that numerous clinical laboratories were able to bring up laboratory-developed tests (LDT) quickly that were effective. But over the next 10 years or so, the regulatory public health establishment put in barriers that made it difficult for a qualified lab to bring up an in-house test for a novel infectious agent. That became an issue at the start of the SARS-CoV-2 pandemic when there were COVID-19 assays developed by clinical labs that were ready to go in early 2020. Do you want to comment on how the regulatory establishment has made it more difficult for a qualified lab to bring up an LDT quickly in response to an outbreak?

SALERNO: What I can say is that our public health system needs to have ways of engaging highly qualified technical experts in clinical laboratories and instrument manufacturers, especially to support new test development, at the onset of a potential outbreak. We need to understand how the regulatory system can best support and adapt to that demand.

EDITOR: How would you see the path forward?

SALERNO: Again, it comes back to my earlier point, which is that the clinical laboratory community now needs to think of itself as part of the public health community. And vice versa, the public health community needs to see the clinical laboratory community as a valuable contributor to public health and public health responses. It's fair to say that three years ago, these were two silos that largely didn't interact with one another. That caused challenges for us as a nation at the onset of the pandemic. These communities need to continue to work together more seamlessly. We need to envision a laboratory system that crosses public health and private sector boundaries and learns how to collaborate with one another.

EDITOR: How should the public and private laboratory sectors view each other?

SALERNO: The public health community needs to see the clinical laboratory community as an asset, and the clinical laboratory community needs to see public health as part of their mission. Our division is really at the center of that from the CDC perspective. And that is one of the main objectives that we continue to pursue: How do we build those relationships and that capacity, and how do we provide more information to the clinical and commercial laboratory community, including the hospital community, to make them all feel genuinely part of public health? And then how do we address the challenging regulatory issues that can bring the private sector to bear more quickly during responses?

EDITOR: What are your thoughts about the monkeypox outbreak response in the spring and summer?

SALERNO: Overall, I think the response has gone well, but, of course, opportunities still exist to improve. Again, this year's monkeypox outbreak presented us with a slightly different scenario. We had a CDC test for monkeypox, but the clearance from the FDA limited the test to the **Laboratory Response Network**, which includes our public laboratories. When we realized that we needed access to testing more quickly, and we needed

to distribute that test more widely than the Laboratory Response Network, it took some time. However, we were able to get our tests distributed to five large commercial laboratories within a month, and we increased our test capacity from 6,000 tests a week in the Laboratory Response Network to over 80,000 tests per week once we added those five commercial laboratories.

EDITOR: What factors made this distribution difficult?

SALERNO: It was difficult because we weren't able to offer the test to everybody. The CDC has limited test kit manufacturing capacity, and CDC is not well suited to provide testing reagents to all testing laboratories. This is a good example of where we need help from the private sector, and where we still need to implement better systems and processes to access that help more quickly during public health responses.

EDITOR: Were clinical laboratories responsive to this need?

SALERNO: Yes. The laboratory community was very receptive to CDC early in the monkeypox response, asking if they could help. That was a huge benefit. With the monkeypox response, even though it wasn't fast enough, my opinion is that the rapid expansion of access to monkeypox testing helped to quickly identify new cases and reduce the amount of transmission. Overall, I feel good about how the clinical laboratory community contributed to the nation's monkeypox response.

EDITOR: What will unfold in 2023 for CLIA regulation updates and CLIAC activities that CLIA-licensed laboratories would be interested to know about ahead of time?

SALERNO: The important thing to talk about is that three CLIAC work groups are currently operational. The first is the **CLIAC Regulatory Assessment Work Group**. It is examining three reports that were presented at CLIAC in April 2019. One report was on CLIA personnel regulations, one was on non-traditional workflow models, and the third was on next-generation sequencing.

Key Online CDC Resources for Labs

AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S DIVISION OF LABORATORY SERVICES (DLS), there is a Q&A that mentions several free resources that clinical lab directors may want to review:

- **DLS Laboratory Trainings**: This page offers more than 40 training courses for clinical laboratories. *www.cdc.gov/labtraining/*
- **Laboratory Outreach and Communication System** (LOCS): LOCS provides frequent alerts and advisories to the clinical laboratory community. *www.cdc.gov/locs/*
- **LOCS Calls**: These calls take place every third Monday of the month at 3 p.m. Eastern and feature experts from federal health agencies and elsewhere. *www.cdc.gov/locs/calls/*
- **OneLab Network**: OneLab offers training (including virtually), webinars, and job aids for registered members. *www.cdc.gov/labtraining/onelab/network.html*
- **OneLab Rapid Education and Capacity-Building Hub** (REACH): OneLab REACH provides a lab-based learning management system vetted by experts. *reach.cdc.gov/home*

EDITOR: Is there progress with these CLIAC initiatives?

SALERNO: The CLIA Regulatory Assessment Work Group is now integrating those three earlier reports and saying, "There's a number of elements within the CLIA regulatory framework that are out of date." CLIAC asked that work group to look at those three prior reports and consider how the CLIA regulations should be updated. In my opinion, this is the most assertive CLIAC has been in convening work groups and assigning them mandates regarding the need for revision of the CLIA regulations.

EDITOR: Does this work group have a timetable?

SALERNO: This work group will present a report at the November CLIAC meeting. That will be interesting. I anticipate that CLIAC will begin to pressure the federal government to make more substantive changes to the CLIA regulations.

EDITOR: What are the other two CLIAC work groups doing?

SALERNO: One is focused on CLIA certificate of waiver and provider-performed microscopy laboratories. That work group will also present to CLIAC in November. There is also a next-generation sequencing [NGS] work group, sort of a second-generation work group on NGS. And it will present in April 2023. I believe these three work groups will enable CLIAC to make recommendations to the federal government for the most substantive CLIA reforms, perhaps in the history of CLIA.

EDITOR: What do you think lab leaders should know about the Department of Laboratory System's offerings as they head into the next year?

SALERNO: The Division of Laboratory Systems' website is one of the best websites at the CDC. All of our work is presented on that website in a user-friendly format. For a several years now, we've had a next-generation sequencing quality initiative underway. That section of our website has over 90 free products to help clinical laboratories implement quality systems if they're using NGS tests. This has been a challenge for CLIA because NGS did not exist in the early 1990s when the first CLIA regulations were written and published. So, we've worked hard over the last few years to convene experts from across the community to develop NGS products and tools that we can make freely available to everybody.

EDITOR: Does the DLS website have other information of interest to clinical laboratories?

SALERNO: Another program we started in 2020 is the **OneLab Network**. The idea was to connect clinical and public health laboratory professionals to build an ongoing learning community. We develop training, webinars, and job aids, as well as some of our virtual reality work. OneLab Network now has over 2,500 members. They meet virtually every month, and we solicit feedback from members. I think it's a fabulous concept, and it's growing very quickly.

EDITOR: Are there any new developments in 2022 with OneLab?

SALERNO: Yes. This summer, we started **OneLab Rapid Education and Capacity-Building Hub**, or REACH. It's a free, CDC-created laboratory training platform customized to the needs of the clinical laboratory community. This is the first time this sort of learning management system has ever existed at a federal level. It's a great resource for the entire clinical laboratory community. It gives small clinical laboratories that don't have their own learning management system the opportunity to use this pre-existing CDC system on their own. Laboratories can put all their own people into it and have confidence that the training courses from OneLab REACH have been vetted extensively by subject matter experts. For laboratories that do have their own learning management system and want more robust tracking of their staff's training scores and progress, we also offer free syndication of our eLearning courses. All of this information is available at www.cdc.gov/onelab.

EDITOR: Thank you for sharing all this information about activities at the Division of Laboratory Systems. This will help our clients and regular readers understand how they can better collaborate with your division and tap the information that you make available on your website.

SALERNO: We appreciate the opportunity to share our lessons learned in recent years, along with all the services we offer to clinical laboratories. TDR

Ravgen Gets $272.5 Mil Verdict against Labcorp

Quest Diagnostics quickly settles similar litigation with biotech company over patented genetic tests

CEO SUMMARY: In September, a jury returned a $272.5 million verdict against Labcorp, representing royalties owed to biotech company Ravgen for infringement of its diagnostic genetic test patent. Soon after, Quest Diagnostics settled a similar lawsuit with Ravgen before its trial began. The victories against the two largest commercial labs illustrate the risks of navigating genetic testing patents and what is considered fair use by competitors.

After a favorable jury verdict and subsequent quick settlement involving the nation's two largest commercial laboratories, it remains to be seen what further action **Ravgen** may take in response to alleged patent infringement of two prenatal genetic tests.

The last few weeks have been eventful for the biotech company in Columbia, Md. On Sept. 23, a jury returned a guilty verdict against **Labcorp** for infringing upon Ravgen's intellectual property. Labcorp now owes Ravgen $272.5 million dollars as part of the verdict.

Then, on Oct. 7, **Quest Diagnostic** settled a similar lawsuit from Ravgen for an undisclosed amount just days before the trial was to begin. By all appearances, Quest did not want to risk a negative jury verdict and the publicity surrounding it.

Ravgen lead attorney Robert Desmarais, Founding Partner of **Desmarais LLP** in New York, did not return a request for comment from The Dark Report. However, in a statement, Desmarais said the Labcorp verdict brings back a measure of credit to Ravgen that it lost for its testing development work.

"The verdict demonstrates the originality of Ravgen's patent, which was foundational for the creation of non-invasive prenatal genetic testing," Desmarais stated.

Labcorp is 'Disappointed'

In a statement sent to The Dark Report, Labcorp said it is considering appealing the verdict.

"We believe that Ravgen's claims are wholly without merit and, therefore, we are disappointed with the jury's verdict and are reviewing our options for an appeal," Labcorp wrote. "In addition, Labcorp has instituted proceedings before the Patent Trial and Appeal Board of the **U.S. Patent and Trademark Office** challenging the validity of the Ravgen patents, with decisions on validity expected in November and December 2022."

The lawsuit contended that Ravgen Chairman and CEO Ravinder Dhallan, MD, PhD, developed and patented a test for cell-free fetal DNA screening. Patent No. 7,332,277 is titled "Methods for Detection of Genetic Disorders." The patent was issued in February 2008.

Ravgen claimed Labcorp and its subsidiaries were aware of the patent since at

least 2011. Nonetheless, Labcorp marketed two of its own DNA tests—MaterniT and informaSeq—that borrowed intellectual property from Ravgen's work, according to Desmarais.

"Despite its knowledge of the patents-in-suit, and of its infringement of those patents, Labcorp has continued to willfully infringe the patents-in-suit so as to obtain the significant benefits of Ravgen's innovations without paying compensation to Ravgen," the lawsuit argued.

Labcorp sold more than 2.7 million of these tests. The jury awarded $100 in royalties to Ravgen for each of those tests, totaling $272.5 million.

Quest did not respond for comment about its settlement. The Ravgen lawsuit against Quest centered on the latter's QNatal Advanced genetic tests, according to *Reuters*.

Ravgen also filed similar lawsuits against other companies over their DNA tests, including **Illumina**, **Natera**, and **Roche's Ariosa Diagnostics**, *Reuters* reported.

Past Royalty Demands

What happens next with Ravgen will be of interest to laboratory and pathology managers given the history of genetic test litigation over the past two decades.

In 2004, upon receiving a patent verdict in its favor (also against Labcorp), **Competitive Technologies, Inc.** sent royalty demand letters to hundreds of labs. The letters requested that the labs pay for performing past homocysteine tests, which were the subject of its suit against Labcorp. Such royalty payments financially impacted many labs and hospitals.

At the time, The Dark Report wrote that hundreds of biotech companies were researching molecular markers for drugs and diagnostic tests. *(See TDR, "Facing Down the Lab Assay Patent Monster," Nov. 1, 2004.)*

"Patent protection of their discovery is the end goal," TDR noted. "At some future point, the laboratory industry will have to square off with the patent/royalty monster. It remains to be seen whether the monster can be tamed, or whether it will wreak havoc on the financial condition of the nation's laboratories."

Since then, genetic testing development has flourished. There are an estimated 175,000 genetic tests on the market today from U.S. labs, according to **Concert Genetics**. *(See TDR, "Coverage, Reimbursement Still Difficult for New Lab Tests," Aug. 8, 2022.)* TDR

Bill Would Amend Patent Law for Some Diagnostics

Should the Patent Eligibility Restoration Act of 2022 (S.4734) currently before Congress be passed, it would amend current patent law, including for diagnostic tests.

The bill, introduced by U.S. Sen. Thom Tillis (R-NC) in August, makes exceptions for areas that would not be covered by patents, including human genes.

However, genes that are altered or enriched by scientific methods would be eligible for patents under the proposal, according to the *National Law Review*.

"One of the goals of the bill is to override case law that has made it difficult to receive patents on diagnostics inventions," the *National Law Review* noted.

Some aspects of the bill come from the U.S. Supreme Court's 2013 decision that natural genes cannot be patented.

At the time, that decision was a blow to **Myriad Genetics** in Salt Lake City. Myriad sold a molecular diagnostic test that analyzed the BRCA1 and BRCA2 genes to assess a woman's risk for hereditary breast and ovarian cancer. Myriad held a patent on the genes.

Following the Supreme Court decision, competitors swooped in with their own versions of the test, which lowered prices and reimbursement. *(See TDR, "CMS Cuts BRCA Price by 49% in Response to Competition," Jan. 13, 2014.)*

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Clinical laboratories may soon face increasing pressure to test for respiratory syncytial virus (RSV) now that the public has become aware of the pathogen. Over the past month, there has been an onslaught of media attention on RSV. The coverage has often focused on how this common virus could tag team with influenza and SARS-CoV-2 to create a triple whammy of contagious infections circulating during the fall and winter.

MORE ON: *RSV*

For the week ending on Oct. 22, there were 6,061 RSV cases detected by antigen or PCR testing, according to the **Centers for Disease Control and Prevention**. That number is up 29% from the week ending Sept. 24, which had 4,691 cases. Children under five years old, who are traditionally prime targets for RSV infection, may be more susceptible currently. "The virus is encountering a highly vulnerable population of babies and children who were sheltered from common bugs during the pandemic lockdowns," *PBS News Hour* reported on Oct. 24.

SUMMA HEALTH SELLS OUTREACH ASSETS TO QUEST

Integrated healthcare delivery system **Summa Health,** based in Akron, Ohio, has agreed to sell select assets of its laboratory outreach business to **Quest Diagnostics**. Financial terms were not disclosed. Under the agreement, Quest's laboratories in Twinsburg, Ohio, and Pittsburgh will provide testing for physicians and patients serviced by Summa Health's outreach business. Summa Health will continue to operate its hospital labs that provide services for inpatient and hospital-based outpatient care. The move is the latest in a long line of lab outreach sales to large commercial laboratories. Just back in August, **Labcorp** acquired the lab outreach business of **RWJBarnabas Health** in West Orange, N.J. A factor that frequently motivates health systems to sell lab outreach programs is the need to raise significant amounts of capital to offset operating losses and bolster the system's assets.

TRANSITIONS

• Scott Kilpatrick, MD, is the new Medical Director of Anatomic Pathology at **Cleveland Clinic Laboratories**. He will continue to serve as Director of Orthopedic Pathology and Co-Director for the Center for ePathology at **Cleveland Clinic**. He previously worked at **Novant Health Forsyth Medical Center**.

• Jennifer Schleit, PhD, FACMG, has been appointed as Laboratory Director at **Rady Children's Institute for Genomic Medicine** in San Diego. Prior to this, she was laboratory director at **Blueprint Genetics**.

• **Rush University Medical Center** named Gwendolyn Robles as Administrative Director, Laboratory. She held prior positions at **Community First Medical Center**, **Lurie Children's Hospital**, and **Mayo Clinic**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 21, 2022.

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- ***What labs need to know about consumer interest in lab tests: Insights from one of the nation's fastest-growing DTC lab firms.***
- ***Strong reasons why 2023's new digital pathology CPT codes are generating optimism within the pathology profession.***

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