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Surprises & Twists
The Year's Top 10 Lab Stories
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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...

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2024: Year of Decision for FDA Regulation of LDTs

For officials at the federal **Food and Drug Administration** (FDA), it's been a long road to gain the power to regulate laboratory-developed tests (LDTs). It was in 2014 when the FDA sent a notice to Congress of its intention to begin regulation of LDTs.

In the decade since, there has been continuing debate about whether existing legislation gives the FDA the right to oversee LDTs. Proponents and opponents continually assert their positions. One group of supporters succeeded in getting members of Congress to introduce legislation that would specifically authorize the FDA to regulate LDTs. That was the Verifying Accurate Leading-edge IVCT Development (VALID) Act. Drafted in 2018, the proposed bill was first introduced in Congress with sponsors in 2020. Yet, almost four years later, the VALID Act has yet to gain enough support to come to a vote.

Now, about 10 years after the FDA first delivered its notice to Congress that it intended to regulate LDTs, the agency may finally attain that goal. On Sept. 29, 2023, the FDA announced the Medical Devices; Laboratory Developed Tests proposed rule. It received public comments on this rule through Dec. 4.

The entire clinical laboratory industry awaits the FDA's next move. Some experts believe the agency could issue a final rule around April. It would be reasonable to expect that opponents of FDA regulating LDTs would take their case to a federal court in response to this development.

What makes FDA regulation of LDTs a major issue is that thousands of labs in the U.S. perform LDTs daily in support of patient care. The test numbers are huge. One company that keeps a database of genetic tests says test catalogs that it monitors list more than 75,000 genetic tests. The overwhelming majority are LDTs.

Just this fact demonstrates why the FDA's desire to regulate LDTs brings a new set of challenges. Does the FDA have adequate resources and experienced staff to review LDT premarket review submissions? If not, will delays in agency reviews suppress the rate of innovation? The FDA says it will grandfather existing LDTs. But if that number is 75,000 assays, and some number of these tests are known to be unreliable, how will patients be protected if there is no FDA oversight of these grandfathered LTDs? Given the FDA's momentum to deliver a final rule in 2024, it should only take a few more months to learn the answers to these and similar questions. TDR

Year's Top 10 Lab Stories Contain Surprises & Twists

➤2023 may have been mostly peaceful for labs, but this year's stories point to important changes

➤➤CEO SUMMARY: With the SARS-CoV-2 pandemic now in the rearview mirror of the nation's clinical labs and pathology groups, the important news stories of 2023 were mostly about developments where the consequences will influence laboratory operations in coming years. Artificial intelligence (AI) is the exception. AI is number one on The Dark Report's "Top 10 Lab Stories of 2023" because AI will soon be baked into the automation, analyzers, and information services offered to labs.

When looking back at the events of 2023, it was a relatively peaceful year for clinical laboratories and anatomic pathology groups. It lacked the drama of 2020, when the SARS-CoV-2 outbreak dominated everything labs did through 2020 and into 2021.

This year was also different than 2022. During that year, the shortage of clinical laboratory scientists and other lab positions was acute. This staff shortage was aggravated by the double whammy of a continuing supply chain shortage and the burst of inflation which hurt labs even more by increasing the cost of skilled labor, analyzers, and lab supplies. *(See TDR, "2022's Top 10 Lab Stories Confirm Challenging Times," Dec. 12, 2022.)*

Thus, when compared to the three years that preceded it, 2023 was a relatively quiet year. This was a welcome change for lab administrators and pathologists. It was an opportunity to guide their lab organizations back to a level of normality that had not existed since 2019, before the arrival of the pandemic.

The rather quiet nature of the events of 2023 means that The Dark Report's "Top 10 Lab Industry Stories for 2023" is comprised of slower-moving developments. Nothing on this year's list represents an immediate threat or crisis that requires many or all labs to respond decisively or suffer dire consequences. That's good news!

The Dark Report selected artificial intelligence (AI) as the number one story for the lab industry in 2023, not because it is an immediate threat, but because AI is developing new capabilities that companies are quickly integrating into their products and services.

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That means, from today forward, when labs come to market to buy automation, analyzers, and informatics solutions, their suppliers will tout the unique AI features that these products will deliver to labs.

AI, Shortages, PAMA Fee Cuts

To be savvy buyers, lab managers and pathologists will need to understand AI and its enabling technologies. These include deep learning (DL), machine learning (ML), natural language processing (NLP), and neural networks (NNs), to name a few. *(See #1, page 5.)*

Two familiar market dynamics in the lab marketplace made this year's list as well. One is the shortage of skilled lab staff and how some labs are cleverly increasing their local supply of qualified candidates. *(See #5, page 7.)*

Another news story during this year has been a regular on past Top 10 lists. It involves the next scheduled round of PAMA fee cuts to the **Medicare** Clinical Laboratory Fee Schedule (CLFS). Fortunately, Congress voted earlier this month to defer those lab price cuts for one more year. This is the second year in a row that Congress has delayed implementation of the lab price cuts scheduled by Medicare officials. *(See #6, page 7.)*

FDA's Rule to Regulate LDTs

2023 was a year where familiar issues—common to the lab industry in most years—again bubbled up to the surface in ways that require a response by clinical labs and pathology groups.

Without question, the most controversial lab story of 2023 involves regulation of laboratory developed tests (LDTs) by the federal **Food and Drug Administration**. It's been a 10-year journey for the FDA to get to this point. In September, it published a draft federal rule, which, as it says on its website, are "regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory."

This is story number two on our Top 10 List because, should a final version of the rule be implemented (and it survives court challenges by opponents), sometime in 2024, any clinical lab in this nation performing LDTs will need to submit new LDTs to the FDA for premarket review. *(See #2, page 5.)*

Genetic testing makes this year's list with two different stories. One story involved the growing recognition with the wider healthcare community that rapid whole genome sequencing (rWGS) has demonstrated clinical value for newborns—with the added bonus of delivering a true return on investment. Children's hospitals are leading the charge on rWGS. *(See #3, page 6.)*

Genetic Tests with Z-codes

The second genetic testing story on our Top 10 List is the announcement by **UnitedHealthcare** in May 2023 that it would require Z-codes on genetic test claims. This requirement was to become effective on genetic test claims involving about 250 CPT codes submitted as of Aug. 1, 2022, but it has been pushed back until sometime in 2024. It's believed that other major health insurers are watching UnitedHealthcare and are prepared to enact similar requirements if Z-codes help them better understand what genetic tests are being billed and how they help patients. *(See #6, page 7.)*

Of course, the struggling finances of different classes of providers generate regular news headlines these days. The financial travails of these providers are bellwethers watched by labs as they see ongoing erosion in their reimbursement for lab tests.

This is the reason behind the acquisitions and mergers between multi-hospital health systems, typically with one partner to the merger lacking an adequate balance sheet. *(See #9, page 9.)* Financial woes are also haunting the nation's retail pharmacy chains. One has filed bankruptcy and most chains are closing hundreds of retail stores. *(See #10, page 9.)* TDR

2023 #1 Artificial Intelligence: It's a Huge Story across Healthcare and Lab Industry

For hundreds of years, the saying "The King is dead! Long live the King!" was a cultural marker for a major change in leadership at the highest levels of government. Today, artificial intelligence (AI) may aptly fit "the King is dead! Long live the King!" as a statement that radical change is underway.

At the start of 2023, most of us were aware that the technologies incorporated into artificial intelligence were evolving swiftly. But few of us were prepared for the rate of adoption of AI in a host of products and services. *(See TDR, "Artificial Intelligence: Now a Priority for Labs," Dec. 4, 2023.)*

The perfect example is **OpenAI's** ChatGPT Plus. The public was given access to it on Feb. 1, 2023. According to *Reuters*, ChatGPT reached 100 million users faster than **TikTok**, which took nine months to achieve that milestone, and *Instagram*, which made it in two and a half years.

The Dark Report expects that, in the coming 12 to 36 months, almost every product or service presented to a clinical laboratory will include an artificial intelligence-powered solution. This is one reason why it would be timely for lab administrators and pathologists to update their lab's strategies as it pertains to artificial intelligence.

Artificial intelligence is this year's number one lab industry story. It is why the upcoming *Executive War College* on April 30-May 1, 2024, will have a full slate of sessions centered around AI's use in a wide range of lab operations and activities.

2023 #2 FDA's Proposed Rule to Regulate LDTs Triggers Uproar by Those For and Against

This fall, almost a full decade after it sent notice to Congress that it intended to regulate laboratory developed tests (LDTs), the federal **Food and Drug Administration** issued a proposed rule it would use to oversee LDTs. *(See TDR, "FDA Issues Proposed Rule to Further Regulate LDTs," Oct. 2, 2023.)*

Reaction to this draft federal rule was immediate and intense. On one side are those in support of FDA assuming regulatory oversight of LDTs. This includes consumer advocates who offer examples where inaccurate or inappropriate genetic tests—performed as LDTs—caused patient harm.

Also in support of FDA oversight of LDTs are many *in vitro* diagnostic (IVD) corporations. They assert that LDTs do not undergo a comparable rigorous development and review that is required when an IVD firm wants approval to sell a test kit to clinical laboratories.

On the other side are opponents of the FDA's draft rule to regulate LDTs. Most prominent in this opposition are hundreds of pathologists working in medical college laboratories. The **American Clinical Laboratory Association** (ACLA) also opposes this action.

The time for public comment ended on Dec. 4, 2023. During a November webinar for the public, the FDA disclosed that 1,000 public comments had been submitted to the agency as of that date. This shows the intense interest within and without the lab industry on the subject of FDA oversight of LDTs.

2023 3 Children's Hospitals Demonstrate Value of Rapid Whole Genome Sequencing

WHOLE GENOME SEQUENCING (WGS) is a fast-growing area of genetic testing. This is particularly true in children's hospitals, where—for the right reasons—the clinical benefits of rapid whole genome sequencing (rWGS) are attracting much attention.

Several children's hospitals that pioneered rWGS have delivered papers and issued reports about the benefits of such testing. These i nstitutions a re r eporting significant and measurable clinical benefits to a substantial portion of the newborns where clinical indications justified rWGS. Best of all, along with improved patient outcomes, these children's hospitals report a significant return on investment (ROI).

One example is the study published by **Nicklaus Children's Hospital** of Miami of a pilot rWGS program called Project Baby Manatee. During 11 months, 50 children and their families underwent sequencing. Better treatment options resulted for 19 children (38%). Savings of $3.8 million where confirmed, resulting in an ROI for use of rWGS of 76.5%. *(See TDR, "Whole Genome Sequencing for Newborns Gains Favor," Nov. 13, 2023.)*

KFF Health News, produced by the **Kaiser Family Foundation**, reported that eight state **Medicaid** programs have added coverage for rWGS or will soon cover this service. Studies done and published overseas also confirm the value of rWGS for patients with certain conditions.

2023 4 PAMA Cuts to Medicare Lab Test Fees Deferred for One Year by Congress

THIS MONTH BROUGHT A BIG WIN FOR THE CLINICAL LABORATORY INDUSTRY. Early in December, **Congress** passed legislation that defers by one year the PAMA lab test price cuts scheduled to take effect on Jan. 1, 2024. *(See TDR, "Congress Delays PAMA Fee Cuts, Passage of SALSA Act Is Goal," Dec. 26, 2023.)*

This is the third year in a row that Congress has deferred the next scheduled round of price cuts to the Medicare Clinical Laboratory Fee Schedule (CLFS). Cuts that were to take effect on Jan. 1, 2022, will now happen on Jan. 1, 2023. *(See TDR, "Congress Delays PAMA Fee Cuts, Passage of SALSA Act Is Goal," Dec. 26, 2023.)*

Individuals with knowledge about the lobbying efforts in Congress tell THE DARK REPORT that a growing number of elected officials and their key staff members recognize that Medicare officials have been aggressive in how they have interpreted and implemented certain sections of the Protecting Access to Medicare Act (PAMA).

The draconian reductions in the fees Medicare pays for many high-volume lab tests has caused many small labs to close their doors or go bankrupt. Since these lab companies typically serve small towns and rural areas not serviced by the big national labs, their closing causes Medicare beneficiaries to lose access to local care.

With Congress acting three years in a row to defer the scheduled PAMA test price cuts, there is optimism within the lab profession that passage of the SALSA Act is feasible and might even happen in 2024.

2023 5 Some Labs Get Creative In Solving Their Shortage of Clinical Lab Scientists

CREATIVITY IS FUELING THE EFFORTS OF A GROWING NUMBER OF LABS TO INCREASE the supply of desperately needed clinical laboratory scientists (CLSs) and other skilled lab professionals.

One idea that paid dividends involved approaching a local Congressional representative and presenting the case for a federal grant to support training more clinical laboratory scientists.

Consequently, one of the last funding bills passed by Congress last year included $3 million in federal funding for **ARUP Laboratories** to build a new clinical lab training center in partnership with the clinical laboratory division at the **University of Utah School of Medicine**. The training facility is on target to open in 2024 and will enable the project to double to 80 the number of annual medical laboratory science undergraduates. *(See TDR, "ARUP, University of Utah Partner in Center for MT Training," March 6, 2023.)*

In New England, **Dartmouth Health's** lab was challenged with an aging workforce and a rural service area. It adopted an innovative approach of educating high school students about careers in laboratory medicine.

It's a work-to-learn program that incorporates distance learning via **Weber State University's** online MLT program. Dartmouth's Workforce Readiness program and its career ladder are producing CLSs in about three years with a 95% success rate and a verified return on investment. *(See TDR, "Dartmouth Lab Recruits and Trains More MLSs," July 10, 2023.)*

2023 6 UnitedHealthcare Announces It Will Venture into the World of Z-codes

IF THERE IS A GORDIAN KNOT CONFRONTING THE NATION'S GOVERNMENT AND PRIVATE PAYERS, it is how to unravel the complexities inherent in the ever-surging number of genetic test claims submitted by genetic testing companies.

The new twist in this problem is that the nation's largest health insurance company—**UnitedHealthcare**—decided it would require Z-codes with certain genetic test claims. UnitedHealthcare originally set Aug. 1, 2023, as the date when it would require Z-codes for genetic test claims covered by about 250 CPT codes. It delayed implementation of this policy until sometime in 2023.

Processing genetic test claims has become a major issue for health plans. **Concert Genetics** of Nashville, Tenn., reports that more than 75,000 genetic tests are offered in today's market.

UnitedHealthcare insures 40 million Americans. Its decision to require Z-codes with genetic test claims will be closely watched by other health plans.

However, associating Z-codes with genetic test claims (with some genetic test claims using 20 or 30 CPT codes) will be a challenge for any payer, for reasons identified by THE DARK REPORT. *(See TDR's "UHC Z-code" stories on May 30 and Sept. 11, 2023.)*

The importance of this story is that the complexities of processing genetic test claims involving tens of thousands of different types of genetic tests is reaching a tipping point where payers will have the motivation to enact restrictive measures.

2023 7 New Digital Pathology Class III CPT Codes Generate Optimism about DP's Future

EFFORTS TO ADVANCE ADOPTION OF DIGITAL PATHOLOGY resulted in the implementation of new Current Procedural Terminology (CPT) codes for the scanning of glass slides to produce whole slide images (WSIs). The codes became effective on Jan. 1, 2023.

There are 13 new CPT entries for digital pathology. They are all Category III codes, meaning they are temporary procedural terminology codes that do not receive reimbursement. Category III designates emerging services and technologies. *(See TDR, "New CPT Codes Debut for Digital Path Services," Jan. 23, 2023.)*

It is important to understand that this development is less about gaining immediate reimbursement for the digital pathology activities and more about accumulating workflow data on electronic specimen handling and diagnostics.

CMS will use the data from incoming claims that include the Class III codes to monitor adoption of digital scanning, assess its contribution to more accurate diagnoses, and determine if there is justification to evolve to new reimbursable codes for digital pathology.

Throughout 2023, advocates of digital pathology have encouraged pathology laboratories using digital scanners to include the new Class III codes on those claims. Despite the fact that these codes are non-reimbursable, their use on a large volume of pathology claims will provide the data needed to guide future decisions by CMS.

2023 8 Kaiser Buys Geisinger, Demonstrating That IDN Consolidation Will Continue

ONE CONTINUING TREND IN HEALTHCARE is the ongoing acquisitions and mergers between multi-hospital health systems. In 2023, this trend was reinforced by the news in April that **Kaiser Permanente** had signed an agreement to acquire **Geisinger Health**, based in Danville, Penn.

This transaction is expected to close in 2024, subject to regulatory review. Kaiser plans to put Geisinger into a new entity called **Risant Health**. Kaiser stated that it plans for Risant Health to buy as many as five more health systems and reach total revenue of $30 billion to $35 billion over the next five years. *(See TDR, "Kaiser Acquires Geisinger Health in Value-Based Deal," May 8, 2023.)*

The significance of this transaction is it affirms that stronger multi-hospital health systems will be looking to acquire or merge with other health systems.

Another notable example of such mergers of integrated delivery networks (IDNs) was the deal closed earlier this year when **Atrium Health** of Charlotte acquired **Advocate Aurora Health** of Chicago/Milwaukee. This system now operates 67 hospitals in six states. *(See TDR's "Kaiser Acquisition" stories on May 8, 2023.)*

Lab leaders should recognize that consolidation of the hospital industry is ongoing. In this phase, it's health systems acquiring other health systems, thus concentrating ownership into fewer hands.

2023 9 An Important Sign of the Times? Self-Insured Employers Sue Insurers!

PHYSICIANS, HOSPITALS, AND LABORATORIES HAVE LONG ARGUED THAT HEALTH INSURERS have stacked the reimbursement deck against them and cannot be trusted to objectively process and reimburse claims. Now there is evidence that even self-insured employers are losing trust that private payers are handling claims consistent with their contracts.

This is a significant development. It shows that price transparency is important not just to consumers and patients who want to know the cost of health services before engaging a provider, it is also becoming an issue with self-insured employers. This summer, multiple news stories reported examples of self-insured employers filing major lawsuits against their health insurers because the insurers would not disclose the prices they were paying to doctors and hospitals.

In one example in Connecticut, unions representing bricklayers and sheet metal workers in that state sued **Elevance** (formerly **Anthem**) for allegedly not handing over enough requested information about medical claims. Court documents show that Elevance's negotiated rate with **Hartford HealthCare** for one procedure was $21,274. "[Elevance], however, repriced this claim with an allowed amount of $43,490, which is $22,216 more than [102% of] the gross charges, and $926.47 more than the amount Hartford HealthCare billed the member for the care received." *(See TDR, "Big Employers Sue Payers over Price Transparency," Aug. 21, 2023.)*

2023 10 Ongoing Financial Losses Continue to Vex Hospitals and Retail Pharmacy Chains

GENERATING BLACK INK IS PROVING ELUSIVE FOR TWO OF THE NATION'S MOST IMPORTANT HEALTHCARE INDUSTRIES. Over the course of 2023, hospitals (along with their parent health systems) and larger retail pharmacy chains reported operating losses. *(See TDR, "Hospitals, Retail Pharmacy Chains Struggle to Be Profitable," Oct. 23, 2023.)*

The financial struggles of hospitals and integrated delivery networks (IDNs) across the nation regularly are the subject of headlines in national and regional media. For example, in October, the **Washington State Hospital Association** (WSHA) surveyed all the acute care hospitals in the state. WSHA reported that acute care hospitals had $750 million in operating losses during the first six months of 2023.

It is a similar story with the national retail pharmacy chains. In October, **Rite Aid** filed Chapter 11 bankruptcy. It plans to close 900 of its 2,000 stores.

Between 2018 and 2020, **CVS** shuttered 244 stores. It declared in 2021 that it planned to close another 900 stores by 2024. At its peak, CVS operated 9,962 stores as of 2020.

In 2019, **Walgreens** disclosed it would close 200 stores. Last June, it said it would close an additional 150 stores. As of 2022, its website said it operated "almost 9,000 stores."

In the case of retail pharmacies, they have been disintermediated by pharmacy benefit managers (PBMs) and **Amazon's PillPak**. These two players now control most of the prescription market.

Lab Market Update

OPKO's BioReference, Sonic Each Release Earnings Reports

Because of expected declines in COVID-19 testing both lab firms report modest declines in revenue

BELOW IS A SUMMARY OF RECENT FINANCIAL EARNING REPORTS for **OPKO's BioReference Laboratories** and **Sonic Healthcare Ltd's** lab operations in the U.S. This finishes our coverage of Q3-23 financial reporting by the larger public laboratory corporations.

BioReference LABORATORIES

BIOREFERENCE LABORATORIES: 'Consistent Patient Volume' During Q3, Compared to Prior Year

Within OPKO's third quarter conference call, data specific to its BioReference Laboratories division, based in Elmwood Park, N.J., it reported the following Q3 data as compared to the Q3 2022:

- Q3 diagnostics revenue was down 7.8% to $131.7 million as compared to $142.9 million.
- COVID-19 testing revenue decreased $10 million.

In response to questions from financial analysts concerning BioReference Labs, OPKO CFO Adam Logal, discussed the lab division's test volume, stating "total patient volume year-over-year was consistent. It was plus or minus about 0.5%. Sequentially, it continues to be a stable. We are seeing good growth in the specialty lines of testing that the [lab] team has made its focus."

OPKO President Elias Zerhouni next addressed some new managed care contracts. "BioReference has expanded its market access, and our team has also secured new key payers participation agreements in recent months, including in-network status with **CareSource**, one of the largest managed **Medicaid** payer in the country, as well as all of **EmblemHealth** patients."

SONIC HEALTHCARE

SONIC HEALTHCARE USA: Full Year Revenue Down Slightly at -2.8%

Sonic Healthcare Limited, New South Wales, Australia, reported the following performance of its U.S. laboratory division, for its fiscal year ending June 30, as compared to 2022:

Sonic's U.S. lab revenue fell 2.8% to AUS$2.11 billion (US$1.36 billion) from AUS$2.16 billion (US$1.40 billion). This division represents 26% of Sonic's worldwide revenues. Its Australian labs and German labs make up 24% and 19%, respectively, of Sonic's total revenue.

Sonic Healthcare can claim to be the world's largest multi-national lab corporation. Its global revenue for fiscal 2023 totaled AUS$8.2 billion (US$5.4 billion).

In the United States, Sonic Healthcare signed an agreement last week to acquire **Pathology Watch** for a purchase price of US$130 million. The deal is expected to close before the end of 2023. Sonic describes Pathology Watch as "a medical technology business headquartered in Salt Lake City, Utah, USA, which has developed and commercialized an integrated, end-to-end digital pathology platform for skin pathology (dermatopathology)."

Regulatory Update

Congress Delays PAMA Fee Cuts, Passage of SALSA Act Is Goal

For the second time in two years, Congress voted to delay the next round of CLFS lab test price cuts

ONCE AGAIN, THE CLINICAL LABORATORY INDUSTRY DODGED THE MEDICARE FEE-CUT BULLET. Last month, **Congress** passed a bill that included a one-year reprieve to the impending PAMA reimbursement cuts that were scheduled to take place on January 1, 2024.

The lab industry caught a lucky break. On November 1, the **US House of Representatives**, followed by the **Senate**, on November 15, passed a short-term spending package to keep the government funded beyond the November 17 deadline. The one-year PAMA price reprieve was part of that bill.

Financial Distress

The financial distress to clinical laboratories caused by PAMA's implementation of draconian price cuts, beginning in 2018, seems to have caught the attention of many members of Congress. At the time PAMA was passed into law in 2014, the bill was scored by the **Congressional Budget Office** (CBO) to produce $2.5 billion in cuts to the reimbursement paid to labs under the Medicare Clinical Laboratory Fee Schedule (CLFS) over 10 years.

However, the **American Clinical Lab Association** (ACLA) noted that the last three rounds of price cuts to the CLFS have already surpassed $4 billion, before the further round of cuts that was scheduled for next year.

There is much support within the clinical laboratory industry for passage of H.R. 2377/S. 1000, the Saving Access to Laboratory Services Act (SALSA). According to ACLA, SALSA would ensure patient access to laboratory testing services, protect clinical lab infrastructure, and support innovation in testing advancements.

Under SALSA, CMS would be directed to use a different approach to collect the prices paid by private payers for lab tests. CMS would then use this data to produce accurate and sustainable Medicare rates for lab services.

"The one-year delay is essential and, in 2024, we will continue partnering with the 70 patient and provider organizations and the bipartisan and bicameral SALSA champions in Congress to advance SALSA as a sustainable, long-term solution to this problem," said ACLA President Susan Van Meter in a statement.

"We have strong support from bipartisan sponsors in the House and Senate [for the SALSA Act]," explained Erin Morton, Partner at lobbying firm **CRD Associates**, which represents the **National Independent Laboratory Association** (NILA) in an interview with THE DARK REPORT.

"There's not a concern with the policy itself, but there are concerns with the cost, which has been one of the biggest challenges in getting the bill to move quickly," she added. "But from a policy perspective, lawmakers agree this needs to happen."

The passing of SALSA is needed to correct the flaws in PAMA, and both Morton and Van Meter believe SALSA will be passed in 2024. A dualistic approach is

being undertaken in regard to PAMA reform. "I'll say it's twofold," Morton said. "It is to ensure that the [private payer price] data collected is representative of the entire market, while also making sure that there are some protections for labs."

Rates at Sustainable Level

Should the SALSA Act pass, "our hope is that CLFS rates will be adjusted to where we reasonably think they should be after they were cut more deeply than anyone anticipated," Morton continued. "Getting those rates back to a sustainable level is really important.

"It is going to harm patient access to lab tests if labs continue to face additional fee cuts," she said. "We will see infrastructure issues and loss of staff, especially for NILA members who serve populations that aren't always served by the large, national labs.

"We have many lab members who serve nursing homes, long-care facilities, and underserved urban and rural areas," Morton explained. "If we see some of those community and regional labs close, patient access to lab tests is going to be more challenging for some at-risk populations.

"There is a difference in how close the lab is to the patient," she continued. "We know that proximity to the lab matters in terms of turnaround time and service. For example, sending a phlebotomist to a nursing home to do a specimen collection is the type of service that could be lost."

"CMS [**Centers for Medicare and Medicaid Services**] has gone as far as they are willing without legislative changes," Morton said. "Changing the data collection methodology needs legislative directive. CMS has done what it thinks it was told to do by the original statute. And that's the stance it will take until a new statute is passed."

If SALSA passes, Morton feels some CLFS reimbursement rates will increase which will be beneficial to the entire industry. She said that the top priority is passing full reform and that it is imperative labs do not face additional cuts.

"The SALSA bill changes the way the prices paid by private health plans are collected, but it is not drastically different from the current model," Morton observed. "It will analyze that data from across the entire industry. The goal is to make sure that private payer price data is collected from a representative sample of the industry.

"The biggest benefit [of SALSA] is going to be sustainability in the CLFS rates and hopefully avoiding additional fee cuts," Morton suggested. "The objective is to use a methodology that will last into the future."

Morton said it is important for people to get involved in the process. There have been great responses and good engagement from NILA members in terms of outreach because this topic matters so much to them.

More Co-sponsors for SALSA

"We do a lot of grassroots advocacy with NILA members. We provide materials for them to contact their members of Congress and talk about the direct impact to their labs. We ask them to get involved because connections to their home districts and states matter," Morton said. "In DC, we spend a lot of time talking with bill sponsors and strategizing around ways to move the bill forward. One of the best ways to move legislation on the Hill is to get more co-sponsors, so we are working on that now."

ACLA has created a "Stop Lab Cuts" campaign to seek Congressional action on the planned Medicare payment cuts to clinical labs. According to the campaign website, the three rounds of payment cuts have totaled up to 10% of revenue and have impacted 72% of tests on Medicare's CLFS.

Lab professionals and members of the general public should contact their representatives in Congress and urge them to support the passing of SALSA. TDR

Legal Update

Violating EKRA Earns Lab Owner an Eight-Year Prison Sentence

Federal prosecution in Arrayit case is being compared with Elizabeth Holmes' Theranos fraud case

THIS MAY BE THE MOST HIGH-PROFILE CASE involving a clinical laboratory and the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). Former **Arrayit Corporation** president Mark Schena was sentenced in October 2023 to eight years in federal prison and ordered to pay $24 million in restitution for his role in a scheme involving healthcare fraud, securities fraud, and illegal kickbacks.

The federal conviction and sentencing of Schena has an interesting wrinkle. His prosecution has drawn comparisons to the infamous **Theranos** case, in which Elizabeth Holmes was sentenced to more than 11 years in prison on a variety of fraud charges.

'Elizabeth Holmes of COVID'

Healthcare attorney Jeffrey Sherrin of **O'Connell and Aronowitz, P.C.**, in Albany, N.Y., described Schena as "the Elizabeth Holmes of COVID." Judge Edward J. Davila, **United States District Court for the Northern District of California**, presided over Schena's case. Davila is the same judge who heard the Theranos case.

The **U.S. Department of Justice** (DOJ) initially charged Schena in November 2020 with healthcare and securities fraud. Then, in May 2021, a grand jury issued a superseding indictment with additional charges involving the kickbacks—commission payments to healthcare marketers who solicited business on behalf of the company.

Schena was charged under EKRA, not the Anti-Kickback Statute (AKS), for the kickbacks. A jury convicted him of all counts on Sept. 1, 2022.

Arrayit, a publicly-traded company founded in 1999, operated a laboratory in Sunnyvale, Calif., that had developed an allergy-screening blood test. The company claimed that its technology could detect 120 allergens from a finger-prick drop of blood.

After the COVID-19 outbreak in 2020, the company also marketed a COVID-19 antibody test even though it had failed to obtain an Emergency Use Authorization from the federal **Food and Drug Administration** (FDA).

Federal prosecutors alleged that Arrayit submitted approximately $69 million in fraudulent or otherwise illegal lab test claims to federal health programs and commercial insurers.

The company's blood test screened for "120 allergens regardless of the medical necessity, availability of the less expensive skin tests, reasonableness, rules against ordering the same test for each patient, or use of such testing in the treatment of each patient," the indictment alleged. The goal, prosecutors argued, was to maximize the claims to federal and commercial payers.

Test Bundling

Testimony during the trial revealed that physicians did not have the option to order fewer than 120 allergen-specific tests. Court documents noted that after

the COVID-19 outbreak, the company bundled the allergy test with its SARS-CoV-2 test, compelling physicians to order all assays while falsely claiming that the antibody test could diagnose active COVID-19 cases.

Securities Fraud Charges

The securities fraud charges arose from numerous false and misleading statements about the company's technology, partnerships and financial health, as well as its failure to provide accurate financial statements to investors and the federal **Securities and Exchange Commission**.

For example, in 2018, the company falsely claimed to have secured an allergy testing agreement with **Sutter Health**, in San Francisco.

During pre-trial motions, Schena's lawyer attempted to have the EKRA charges dismissed, claiming that Arrayit's payment arrangements with marketers did not violate the law. In the motion, he cited a federal civil case where EKRA was a factor: *S&G Labs v. Graves*. The case involved a clinical lab in Hawaii and a former marketing manager named Darren Graves.

Sales Compensation Package

Prior to the passage of EKRA, Graves was paid a base salary plus a percentage of net profits, which were dependent on how much revenue the lab earned from its tests. Following the law's passage, the lab's attorney advised that the old commission-based arrangement was now illegal. The lab changed the compensation package and Graves sued, claiming breach of contract.

"The district court in S&G, in a civil case, held that the compensation package would not violate EKRA because EKRA focuses on referrals of individuals," Sherrin explained. "This employee was targeting physicians as the source of his referrals." *(See TDR, "Labs Should Be Cautious about 'Surprising' EKRA Ruling, February 22, 2022.)* Judge Davila disagreed with the Hawaii court's reasoning and denied the motion to dismiss. *(See TDR, "New Percentage-based Commissions Ruling," July 18, 2022.)*

"The judge in the Schena case said that it's still a referral of an individual, even if it's indirect because you're marketing to a physician," Sherrin observed. "The physician is going to refer the individual."

One key government witness was Marc Jablonski, whose testimony laid out the specifics of how Arrayit paid its marketers. Jablonski was the CEO of **DxSolutions**, an Arizona marketing company that solicited business from healthcare providers on behalf of Arrayit. He was charged with one count of conspiracy in 2021 and later pleaded guilty.

Commissions Paid by Arrayit

Jablonski testified that he was paid a commission amounting to 20% of the claims that insurers paid to Arrayit. Then, he paid a percentage of that income to six to eight sales representatives who covered different regions around the U.S. All, including Jablonski himself, were paid as independent contractors.

He testified that he participated in this arrangement with the understanding that the payments, both from Arrayit and to the salespeople, were illegal under EKRA.

EKRA, he testified, had a "monumental" impact on the lab business. "Most labs—all labs except for the biggest ones like the **Quests** and the **Labcorps** of the world—were paying their employees on a 1099 [independent contractor] basis at that time, and it became law in 2018 that that was no longer legal," he testified. "So all of these labs had to switch how they were paying their employees from a 1099 to a W-2."

Jablonski added that he discussed the new law with Schena, expressing concern that Arrayit marketers weren't being transitioned to W-2 employees to comply with EKRA. Schena, he testified, responded "that it wasn't a big deal; that their attorney had said that it is probably going to be overturned; don't worry about it."

Now that Schena has been sentenced, his lawyers have filed a notice of appeal, according to court documents.

"We don't know what he's appealing yet because briefs haven't been filed," Sherrin said. "But presumably, he's going to argue that EKRA doesn't apply in this case. He may have other grounds for appeal, trial errors and things like that. So, we really only have one court decision from a lower district court. At this point, nothing is binding on any other court."

EKRA, Anti-Kickback Statute

Passage of EKRA has upended the approaches used by clinical laboratories to compensate marketing personnel.

As interpreted by the DOJ, the law makes it illegal for a laboratory to pay commissions on referrals based on how many tests it performs or how much it receives from payers. Under the law, those payments could be regarded as illegal kickbacks.

EKRA prohibits individuals from soliciting or receiving "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory," the law states.

"I would describe EKRA as a puzzle," Sherrin said. "It's ambiguous. In its first draft, it wasn't intended for clinical laboratories. Its focus was substance abuse treatment facilities. In its final iteration, the statute included laboratories."

EKRA, AKS Differences

That narrow focus on specific types of healthcare providers is one of several differences between EKRA and the Anti-Kickback Statute, Sherrin said. Whereas AKS applies strictly to claims submitted to federal health programs, "EKRA applies irrespective of who the payer is," he noted. "You don't have to be billing **Medicare**, **Medicaid**, **Tricare**, or any federal payer. You can be billing a private health plan, such as **Empire Blue Cross**."

But the biggest consequence may be that EKRA lacks all the safe harbors

Federal Prosecutor Discussed EKRA, AKS

ONE OF THE PRESECUTORS IN THE FEDERAL FRAUD CASE AGAINST MARK SCHENA was Jacob Foster, currently Principal Assistant Chief of the criminal fraud division for the Department of Justice (DOJ). Attorney Jeffrey Sherrin of O'Connell and Aronowitz, P.C., noted that Foster discussed EKRA and the Anti-Kickback Statute during an **American Bar Association** event in December 2022.

At the event, Foster reportedly stated that because healthcare fraud is rampant, the DOJ will go after cases truly deserving of prosecution. These would be cases with "plus factors." These factors include:

- Did the defendant know his or her conduct was wrong?
- Did he or she continue the behavior after being warned?
- Was there patient harm or overutilization of unnecessary services?

During a Q&A session, Foster was asked whether the DOJ would prosecute a case simply due to a percentage sales agreement. His answer was reportedly "no."

Still, given the uncertainty, Sherrin advises labs to tread carefully to ensure that they're in compliance. "You don't want to be a test case," he said. "Labs should put their salespeople on salary under written agreements that set out all the terms. Don't commit any fraud in the testing, and don't pay off doctors or other providers to send patients."

contained within the AKS. For example, the AKS contains a safe harbor that allows payments of commissions to *bona fide* employees. "But it's a different story under EKRA," he pointed out.

Lack of Case Law for EKRA

According to Sherrin, one factor that makes EKRA a puzzle for attorneys is the lack of case law, where appellate courts interpret the meaning of legislation as it applies in specific cases. For example, is it illegal to pay commissions to independent contractors?

"The government's position is that these arrangements violate EKRA," Sherrin noted. "But there's a lot of disagreement among healthcare attorneys about whether that's sufficient for a criminal charge."

Adding to the puzzle is the intersection between the AKS and EKRA. "There are cases in which both could apply," Sherrin said. But the federal preemption provision in EKRA states that if conduct is prohibited under the AKS, then EKRA doesn't apply.

"So, let me turn that around," Sherrin said. "If it's legal under the Anti-Kickback Statute because it fits within a safe harbor; and if labs have adopted employment and compensation contracts in reliance on the judgment of **Congress** that such arrangements should not be deemed illegal; then why should that same conduct now be held to be illegal under a different statute?"

Salary versus Commissions

Sherrin also questioned why it makes sense for the federal law to differentiate between paying a straight salary and paying commissions.

"Let's say a lab pays someone on a commission basis," he said. "Assume also that there are no forms of illegal inducements offered to referring physicians. When these sales reps are successful, they earn more money. Why is that an illegal kickback?

"Similarly, if the employee gets a straight salary of $200,000 and doesn't do a good job, he or she isn't getting $200,000 in year two, right? Even on salary, they're still incentivized to acquire business. Isn't a lab incentivizing an employee to get business simply by compensating him or her?

"That's one of the issues related to how broadly payments should be considered kickbacks," he continued. "Every business has sales and marketing personnel. So, why is it now that a criminal prosecution can be triggered by this form of payment to that salesperson?" TDR

Defendant Schena Defrauded Investors

Defendant Mark Schena was quite a colorful charlatan, based on court documents filed by federal prosecutors. Schena was accused of fraud.

Schena was originally charged with defrauding investors and the public. A superseding indictment added new counts of healthcare fraud and conspiracy allegations. It was charged that "Schena conspired with others to pay kickbacks, administer fraudulent and unnecessary testing, and to make false and fraudulent statements about the existence, regulatory status, and accuracy of an Arrayit COVID-19 test."

Court documents and testimony in the case showed that Schena, as president of Arrayit Corporation, defrauded Arrayit's investors by claiming that he had invented revolutionary technology to test for virtually any disease using only a few drops of blood.

Prosecutors alleged that Schena and his publicist told investors that Schena was the "father of microarray technology." Another false assertion was that Schena was on the shortlist for the Nobel Prize! Testimony during the trial described how Schena falsely asserted that Arrayit could be valued at $4.5 billion, based on revenues represented to be $80 million per year.

Virchow
Medicine ➤ Money ➤ Managed Care

This column is named after the famous German pathologist, Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

Why Payers Bristle as Labs Submit Inpatient Fees for Outreach Tests

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of The Dark Report better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

One growing source of friction between private payers and the labs of hospitals and health systems is when hospital lab outreach businesses submit claims to payers using hospital inpatient lab test prices.

For payers, hospital laboratory outreach businesses are a big concern. More and more physicians are not independent, they work for a health system. So, hospitals bring in samples from their contracted physicians, bill those lab tests through their hospital's chargemaster, and the patient ends up paying more for the laboratory test.

CBC Price Differences

For example, if a patient gets a complete blood count (CBC) test from a freestanding lab or a national lab's service center, that test is normally about $30. But if the patient gets the test through a hospital lab and it's billed on the hospital chargemaster, it ends up costing $300 or $400.

Payers generally don't like that arrangement because it thwarts the idea behind paying for inpatient services. In an ER or ICU, lab tests and other services need to be STAT. If ER doctors order a troponin test to figure out if a patient is having a heart attack, they need the results quickly. Thus, health plans are going to pay a premium for that urgent test in an inpatient setting.

However, payers started to notice when systems began billing inpatient rates for people who came into the hospital for a basic CBC test. That's not the intent of inpatient billing.

Instead, these basic lab tests should be run outside the hospital, either in an outpatient setting or in a freestanding lab. The rates for these tests ordered by physicians in ambulatory settings are lower because they are routine procedures and not urgent.

There has also been a recognition by private payers that the high volume of routine tests ordered by office-based physicians do generate economies of scale for medical laboratories. That is another reason why prices for outpatient lab tests are lower than for inpatient lab tests.

In recent years, some health plans made changes in response to concerns over the use of hospital inpatient pricing for outreach testing. For example, In 2020, **UnitedHealthcare** (UHC) came out with a new policy stating that a hospital's contract does not allow that organization to be in the lab outreach business. Instead, UHC said hospitals needed to sign a separate contract if they wanted

to do outreach, and those outreach lab tests would be billed at a lower rate. *(See TDR, "New UnitedHealthcare Policy for Hospital Reference Tests," March 9, 2020.)*

In other words, if hospitals doing business with UnitedHealthcare wanted to establish a lab outreach program, they needed to contract with UHC as a free-standing lab and accept the lower reimbursement rates common for outpatient tests. That move created a big hoopla.

Inspecting UB Forms

Payers also know how to scrutinize uniform billing (UB) submissions from hospitals, which are sent to insurance companies. If a patient is in the ER, typically there will be all kinds of STAT services that day. Yes, there will be lab tests, but there's also going to be charges for IV fluids and maybe scans.

The big clue to a payer is if a UB only lists one thing: a laboratory claim for hundreds of dollars. That probably isn't for an inpatient service.

Nonetheless, if a hospital lab submits a UB based on the inpatient chargemaster, the health plan needs to pay that claim because it's part of the hospital's contract with the payer. But if the payer notices outreach claims being billed at the higher rates, it might contact the hospital in question and discuss how the contract is worded.

Payers can also start sending so-called redirection letters to the doctors who send tests to the hospital lab. The nastygram might say: "We notice you are using (five-star hospital's) laboratory for tests for outpatient members. Please use an in-network, freestanding laboratory instead."

Sometimes health plans take it a step further and send patients a comparison of hospital laboratory prices on the chargemaster versus freestanding lab prices for the same test. That lets patients see the difference in what they might pay for routine bloodwork. Patients in high-deductible health plans have an incentive to select lower-priced providers, including clinical labs.

Some hospital-employed physicians will argue that they want to use the hospital for all their tests—inpatient and outpatient—to establish a longitudinal patient record. That way, the doctor can see what a patient was tested for over his or her lifetime, regardless of the setting.

That benefit does have sway with payers. But if the hospital lab sets up its outreach correctly, those outpatient lab tests still performed in the hospital lab will be billed using outreach prices. In this arrangement, physicians continue to get a longitudinal record within the hospital, and the member is not overpaying for a routine test.

Setting Up Outreach

Despite these limitations, some health systems have been very successful setting up outreach laboratory programs that are fully competitive with the national labs, both with test prices and the services they offer. These outreach labs work with doctors that they know from the local hospital, and the patients are happy because they're not getting gouged on pricing. *(See TDR, "Outreach Nets Hospital Lab $2.5 Million in One Year," Oct. 14, 2023.)*

Given these developments, today, if a hospital lab wants to start or reestablish outreach services, the first step from a payer perspective is to reach out to their contact at the health plan. That contact may pass the lab over to whomever handles what's known as ancillary lab contracts. The ancillary folks can spell out what the reduced rates will be for outreach testing.

Some hospitals don't want to accept the fact that they're not going to get that chargemaster rate. I understand why—that higher test rate is gravy to them.

But it is possible to earn revenue by doing outreach at volume. Some small hospital labs can give the national lab companies a run for their money if the doctors all circle around the local hospital lab—and the local lab offers competitive services and test prices. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Is the world ready for a diagnostic service that performs a whole genome sequence of embryos conceived by *in vitro* fertilization? That's the business plan announced on Dec. 5 by San Francisco-based **Orchid Health**. In covering this development, *Science* wrote, "Find the embryo at lowest risk for a disease that runs in your family, touts the company's website. The cost: $2500 per embryo." *Science* also described the service: "Orchid will look not just for single-gene mutations that cause disorders such as cystic fibrosis, but also more extensively for medleys of common and rare gene variants known to predispose people to neurodevelopmental disorders, severe obesity, and certain psychiatric conditions such as schizophrenia."

MORE ON: *Orchid*

News of Orchid's plans met with criticism by scientists associated with **The Psychiatric Genomics Consortium** (PGC). This is a global group of hundreds of researchers dedicated to "decoding the genetic and molecular underpinnings of mental health conditions." PGC asserts Orchid is incorporating PGC data in violation of restrictions against the data's use for embryo screening. Pathologists and lab managers may want to monitor how this story plays out. Critics of this type of genetic screening point out that polygenic risk scores are not yet reliable ways to predict disease risk.

KLAS REPORTS ON DIGITAL PATHOLOGY

Last month, **KLAS Research** of Pleasant Grove, Utah, issued a report: *'U.S. Digital Pathology 2023 Performance Insights.* **Philips**, the manufacturer of a digital pathology product suite, issued a press release about the report's findings. The company stated that, "Since 2019, Philips has helped more than 300 customers and over 20 hospital pathology laboratories go fully digital, meaning that 100% of their pathology slides are digitally scanned, digital diagnosis is the default workflow for the laboratory, and the majority of the lab's pathologists work digitally from anywhere." Philips also wrote that 35 pathology labs currently use Philips' pathology solution in combination with **Ibex Medical Analytics'** Galen AI diagnostics platform. It stated that "use of the Ibex Medical platform has been shown to achieve productivity gains of up to 37% and very high accuracy levels across multiple tissue types." Pathologists may find this information helpful in monitoring the progress of adoption of digital pathology.

TRANSITIONS

- **Roche** subsidiary **Foundation Medicine** appointed Daniel Malarek as CEO. In his 17 years with Roche, he has served in several countries in Europe and Asia.
- **Adela, Inc.** of Foster City, Calif., announced Lisa Alderson is its new Chief Executive Officer. Alderson formerly held positions at **Genome Medical**, **Invitae**, and **Genomic Health**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, January 16, 2024.

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UPCOMING...

- ***Attorney reviews significant EKRA court cases, explains the relevance of each judge's decision.***
- ***New developments in point-of-care testing create value-added opportunities for hospital labs.***
- ***Will public comments about the FDA's draft LDT rule trigger major changes in the draft rule's language?***

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