Volume XXVI, Number 12 Tuesday, September 3, 2019

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
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What Comes Next for the Pathology Profession?

IT MAY NOT BE A COINCIDENCE THAT MANY RECENT NEWS CYCLES have more negative pathology news than positive pathology news. After all, laboratory medicine is at the core of most clinical care delivered to patients, so it's no coincidence that pathology—both clinical and anatomic—is a prime target for government and private payers, along with federal investigators.

The news cycle of the past 60 days makes up the intelligence briefings in this issue. Our lead story on pages 3-8 deals with recent actions by the federal **Food and Drug Administration** (FDA) to put pharmacogenetics testing labs on notice that they must follow federal regulations and guidelines. You'll read about the confusing elements of the agency's actions and why some lab industry experts believe the FDA is overstepping its existing regulatory authority.

Many pathologists use companion diagnostic tests, particularly to diagnose cancer patients and guide physicians as they make treatment decisions. Thus, the FDA's unexpected actions to warn labs performing pharmacogenetics (PGx) tests to comply with appropriate laws and regulations is a disruption to the PGx market. It also increases the risk that a lab and its pathologists can be investigated and sanctioned for non-compliance.

Another negative news story for pathology involves **Anthem, Inc.** and its plan to cut anatomic pathology professional component (PC) prices by 50% to 70% for many pathology CPT codes. Anthem is also shifting anatomic pathology (AP) contracts from its professional services division to its ancillary services division. As you will read in our coverage on pages 9-12, multiple pathology consultants interviewed by THE DARK REPORT concur that this will disrupt long-standing local physician-pathologist relationships. They say these fee cuts also have the potential to affect patient care negatively.

Probably the most unusual bad news story for pathology recently is the arrest and indictment of an Arkansas pathologist who worked for a **Veterans Administration** hospital in that state. He now faces three counts of involuntary manslaughter, along with 28 other criminal counts. He is accused of working while under the influence of alcohol and drugs. *(See pages 13-16.)*

These different bad news stories also demonstrate that the pathology profession lacks effective public communications. There is no credible, recognized entity or individual who can speak on behalf of pathologists when reporters call. TDR

PGx Labs Concerned by FDA's Statements, Actions

Federal agency is telling genetic testing labs to assess if their PGx tests comply with regulations

CEO SUMMARY: Since April, the federal Food and Drug Administration has taken steps that target clinical laboratories that perform pharmacogenetic (PGx) tests. In response to letters from the FDA, some PGx lab companies have stopped reporting data that predicts a patient's response to certain medications. Some pathologists and lab executives have criticized the FDA's actions about PGx tests as being unclear, confusing, and exceeding its existing regulatory authority.

IN THE BATTLE between the **Food and Drug Administration** (FDA) and the clinical laboratory industry over regulation of laboratory-developed tests (LDTs), the FDA is taking steps that may change ways in which medical laboratories market pharmacogenetic (PGx) tests.

This latest fight started when the FDA sent a letter in April to a PGx laboratory affiliated with a Virginia health system. In its letter, the FDA warned the lab about "illegally marketing" associated with some genetic tests it performs.

Later that same month, the FDA issued an announcement and stated it had contacted certain PGx laboratory companies to express concerns about the claims these lab companies were making about how their genetic test results could be used to determine a patient's response to certain medications.

These two FDA actions were then followed by a series of letters that the FDA sent to PGx labs earlier this summer. In these letters, the FDA asked the labs to interpret its earlier statements about PGx testing from a regulatory perspective.

This raised concerns at the labs receiving these letters because few pharmacogenetic tests have been submitted to the FDA for review and clearance. Most PGx tests are developed and performed as laboratory-developed tests. For this reason, some lab directors and pathologists have interpreted the FDA's actions as meaning the federal agency seeks to expand its power to regulate LDTs.

Those lab executives and industry experts who have seen these letters and studied the FDA's announcements about PGx testing have said the federal agency is issuing unclear and confusing guidance

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

and may be overstepping its regulatory authority.

Until recent weeks, however, only a limited number of pathologists and clinical lab executives were aware of these developments. That changed in mid-August when *GenomeWeb* and later *Stat News* reported on the FDA's actions directed at laboratories performing PGx tests and the reaction to these actions among pathologists and executives at labs that offer PGx tests.

Pharmacogenetic Tests

By way of background, for years, molecular and genetic testing labs have been developing pharmacogenetic tests that physicians use to assess how well patients will respond to certain medications.

In the late 1990s, for example, the FDA cleared a HER2neu test as a companion diagnostic test to determine which breast cancer patients would benefit from the cancer drug Herceptin. Since then, a number of genetic tests have gained clinical acceptance as a tool to identify patients with cancer and other diseases who would respond favorably to specific therapeutic drugs.

For many pharmacogenetic tests, the evidence is well established to the point where the FDA has told the makers of some pharmaceuticals to add what are called black box warnings on their drug labels. The warnings state clearly that the drug in question should be taken only after the patient's physician has reviewed the corresponding pharmacogenetic test results. But for other PGx tests, the evidence is less clear.

Concerns about FDA Actions

All the actions taken by the FDA since April caused leaders at many molecular testing labs to become concerned that FDA regulators were suggesting that only the FDA can determine what pharmacogenetic testing information is scientifically valid. Experts in molecular testing dispute this assertion.

Moreover, the FDA's collective actions targeting PGx tests, and the labs that perform them, have lab directors and pathologists also concerned that the FDA has suddenly begun taking unexplained steps to regulate a field that had not previously been subject to much FDA scrutiny.

These concerns grew after the FDA took actions against labs offering PGx testing without premarket clearance in an attempt to prod those labs to submit their tests for regulatory review, according to reporting by the website *GenomeWeb* on Aug. 16.

The FDA has not issued a formal statement about its intentions. Therefore, PGx labs are scrambling to decide how the agency expects them to respond. Some PGx testing companies decided that the best response was to report only PGx variants detected in patients' test results. These labs are removing any mention of drugs or drug classes from their online marketing materials or lab test reports, *GenomeWeb* reported.

PGx Lab Gets FDA Letter

The first salvo in the FDA's actions to clamp down on provider organizations that promote PGx testing appears to have come in April. It was on April 4 when the agency announced that it had sent a letter to **Inova Genomics Laboratory** in Falls Church, Va., warning the lab about "illegally marketing certain genetic tests that have not been reviewed by the FDA for safety and effectiveness." This lab is affiliated with **Inova Health**, a five-hospital system. *(See sidebar, "FDA's Opening Salvo ... Directed at Inova Genomics Laboratory," page 5.)*

After it sent the warning letter to Inova, the FDA issued a public statement, saying it "reached out to several firms marketing pharmacogenetic tests with claims to predict how a person will respond to specific medications in cases where the relationship between genetic (DNA) variations and the medication's effects has not been established."

FDA's Opening Salvo in Battle over PGx Tests Was Directed at Inova Genomics Laboratory

IN APRIL, THE FOOD AND DRUG ADMINISTRATION ANNOUNCED THAT IT HAD ISSUED a warning letter to a Virginia lab company that the FDA said was "illegally marketing certain genetic tests that have not been reviewed by the FDA for safety and effectiveness."

In an announcement on April 4, the agency said it sent a letter to **Inova Genomics Laboratory** in Falls Church, Va., warning that the lab's tests claim to predict patients' responses to specific medications based on genetic variants.

Key passages from this FDA letter allow pathologists and clinical lab administrators to understand how the federal agency describes its concerns with pharmacogenetic testing, which generally are offered as laboratory-developed tests (LDTs).

'Significant Health Risk'

In its letter to Inova, the FDA said, "Selecting or changing drug treatment in response to the test results could lead to potentially serious health consequences for patients. The FDA is unaware of any data establishing that Inova's tests can help patients or healthcare providers make appropriate treatment decisions for the listed drugs. The action today reflects the agency's commitment to monitor the pharmacogenetic test landscape, and take action when appropriate, to address a significant public health risk."

At the time, the FDA noted that consumers have been embracing genetic testing as a way to understand their individual risks for developing diseases. "With this rise in popularity and availability, we're also seeing significant activity in the field of pharmacogenetics, which is the process of understanding what, if any, role genetics plays in a patient's reaction to particular drugs," the agency said.

But the problem for the FDA was how well these tests have been evaluated.

"Without appropriate evaluation to determine whether these tests work, patients are being put at risk—potentially impacting treatment decisions by providing false promise that they will respond well to a certain medicine or keeping them from using therapies that may benefit them," said Jeff Shuren, MD, JD, Director of the FDA's Center for Devices and Radiological Health.

In particular, the FDA was concerned about PGx tests that claim to predict patients' responses to specific medications when such claims have not been established and are not described in the drug labeling. The FDA continues to warn patients and healthcare professionals that they should not rely on these tests for treatment decisions, Shuren added.

Most firms addressed the FDA's concerns by removing specific medication names from labels, promotional materials, and patient test reports.

In the FDA announcement in April, Janet Woodcock, MD, the Director of the FDA's Center for Drug Evaluation and Research, said the agency was committed to supporting innovation in the area of PGx testing, and added, "We will also be vigilant in protecting against the potential risks and are therefore issuing this warning letter to help protect patients and providers from acting on data that has not been demonstrated to promote the safe and effective use of drugs."

In recent weeks, the FDA has sent letters to PGx testing labs that reference the warning letter it sent to Inova and asks labs to interpret what that Inova warning letter means for them from a regulatory standpoint, *GenomeWeb* reported. The FDA letter does not provide specific guidance about what actions, if any, these PGx labs must take to ensure compliance with FDA regulations, the website added.

One executive reportedly told *GenomeWeb* that the FDA wanted the executive's lab to determine how the letter would apply to the lab's PGx test offerings and marketing materials. Lab directors know that FDA actions can have a chilling effect on sales. Therefore, some lab executives might want to consider filing for FDA clearance for any assays the FDA may consider to be lab-developed tests, executives told *GenomeWeb*.

Unsupported Claims?

Last week *Stat News* reported that the FDA is concerned that PGx labs are promoting the ability of their tests to predict a patient's response to drugs with unsupported claims. Doing so could harm patients if patients start, stop, or switch medications inappropriately, *Stat* reported.

Reports showed the FDA contacted at least four PGx testing companies: **Color**, **Genomind**, **Myriad Genetics**, and **OneOme**. In August, Myriad's stock price fell after it told investors the FDA wanted Myriad to change its pharmacogenetic tests, *Stat* reported.

In an e-mail response to questions from THE DARK REPORT, a spokesperson for OneOme said, "OneOme recently removed all medications from our RightMed test and report. This was in response both to customer requests for a gene-focused report, as well as to conversations with FDA."

Physicians Can Consult

Physicians who order OneOme's tests can still consult with OneOme's pharmacists and doctors, to help them interpret patients' test results, the spokesperson added.

Color and Genomind offer PGx tests with a physician's order, and they told *Stat* they recently changed how they report test results. They made those changes "in response to back-channel conversations with the FDA," *Stat* reported. TDR

—Joseph Burns

FDA Asks 'All of Us' to Hold Back PGx Data

ANOTHER INDICATION that the federal Food and Drug Administration (FDA) wants more oversight over pharmacogenetics testing is an action the agency took involving the **National Institutes of Health's** (NIH) research program called "All of Us."

GenomeWeb reported that the FDA asked program officials at All of Us "to only return to participants information on genetic markers that are in FDA-approved drug labeling. The All of Us program plans to report certain clinically actionable genetic markers, including PGx variants, to participants."

An NIH spokesperson said the program is collaborating with the FDA on an investigational device exemption (IDE) submission, said *GenomeWeb*. Researchers submit IDEs when they want to incorporate gene sequencing to guide patient care as part of a federally-funded study.

In describing lab industry criticism of the FDA's actions directed toward pharmacogenetic testing, *GenomeWeb* said critics "feel the agency is trying to regulate the practice of medicine and control the dissemination of scientific knowledge."

The news website quoted a PGx expert at an academic institution, saying, "A lot of people in the field are of the opinion that the FDA may have reached too far in terms of trying to regulate the knowledge around PGx." The expert asked for anonymity to avoid the FDA's attention.

"Everyone recognizes the FDA has an important role in regulating the claims of a commercial product if [it is] not supported scientifically," the expert told *GenomeWeb*. "But, the notion that they [FDA] are the only ones with the ability to say whether something is scientifically supported or not, that's not even consistent with most of medical knowledge."

Concerns Raised Over Pharmacogenetic Tests

Two issues include lack of training for doctors to order and interpret tests correctly and fraud

CEO SUMMARY: Some executives at pharmacogenetic testing companies are criticizing the federal Food and Drug Administration for its recent actions to exercise oversight over PGx testing. But there is more to the story, said one expert who is a past adviser to the FDA on clinical laboratory testing. One issue is how to educate physicians to understand how to order PGx tests and use the results appropriately. Another challenge is how to curb fraud involving pharmacogenetic tests.

EVIDENCE ACCUMULATES that the federal **Food and Drug Administration** (FDA) wants to increase oversight of laboratory-developed tests—including pharmacogenetic tests. The result is that criticism of such increased oversight has come from the clinical laboratory industry.

Opposition to the FDA's attempts to assert more regulatory authority over pharmacogenetic (PGx) testing is expected, given that executives and investors in PGx lab companies prefer lighter regulation of these tests.

Physicians Need Training

But there is another perspective to consider. Serious concerns are associated with some pharmacogenetic tests and whether physicians have the training and knowledge needed to use this genetic test data appropriately in patient care.

In an interview with THE DARK REPORT, Roger D. Klein, MD, JD, said the FDA is reacting to a lack of understanding among treating physicians about how to use these tests appropriately. "One problem in the area of pharmacogenetic testing is that, in general, physicians have been slow to embrace such testing except in some clearly-defined settings," stated Klein. "Physicians have been slow to adopt these tests because it's not been clear what exactly they should do with the information they get from PGx testing.

"Just because a variant shows there's a potential relationship doesn't necessarily mean you understand what to do with that information in particular patients," added Klein, a pathologist, attorney, and expert in precision medicine.

A past advisor to the FDA and other federal regulatory agencies and policymakers, Klein said one of the problems for laboratories that develop PGx tests is the lack of adequate direction in the clinical literature about how to use these tests.

"That's because the field of pharmacogenetics is in a nascent stage," he commented. "In this stage, the medical specialties have not yet embraced pharmacogenetic testing to a significant degree.

"There are some specific instances where good clinical evidence demonstrates that these PGx tests work and that physicians know what to do with the

information," he explained. "But outside of those few areas, there is limited clinical evidence supporting the use of these tests. Most pharmacogenetic tests in use today are for changes that theoretically affect how patients metabolize drugs.

Uptake in Psychiatry

"One specialty that has been receptive to PGx testing is psychiatry," explained Klein. "These physicians may use pharmacogenetic tests to identify patients who will respond well to certain medications—such as antidepressants—based on their PGx test results."

An issue seldom addressed by executives at many PGx labs is the lack of data supporting the utility of identifying genetic markers and the lack of studies demonstrating the results PGx tests provided to physicians and how that information can help them improve patient care. More specifically, many PGx tests offered in the market today don't provide adequate data to support their clinical usefulness.

Asked about this problem, Klein said, "Some labs have promoted such testing on the basis that these assays help certain patients. Other labs may have promoted pharmacogenetic tests based on little or no evidence that testing will benefit patients."

Fraud within the PGx Sector

Also, the potential for fraud exists when PGx labs promote tests that are unsupported by adequate data. Cases of alleged fraud have been reported widely in the field of drugs of abuse testing, for example.

"In the past, we've seen instances where there has been significant uptake of some PGx tests, but that increase in usage was related to fraud and abuse," Klein observed. Such fraudulent behavior taints reputable labs, he added.

"Most of the fraud cases have been related more to a lab's ability to scam Medicare than anything else," he said. "Therefore, I am skeptical the FDA would be any help in preventing it. In some cases, it's possible the tests involved were FDA-cleared. While fraud is a big problem in Medicare, those cases relate more to the ability of the Medicare agency to police fraud than to the FDA status of a test."

Inevitably, any FDA action to regulate pharmacogenetic testing raises concern among lab directors and pathologists that the FDA will require all labs to submit applications for laboratory-developed tests (LDTs). When the FDA has raised the issue of lab-developed tests, the lab industry has pushed back.

The FDA has asserted that it has the authority to regulate all diagnostic tests and can require companies to remove tests from the market if they do not meet FDA's standards. In 2014, the FDA proposed a complex framework to regulate LDTs. *(See "Public Comment Started on FDA LDT Regulations,' TDR, Nov. 3, 2014.)*

LDT Oversight

The FDA later pulled back from that proposal and since then has left oversight of the lab testing industry to the federal **Centers for Medicare and Medicaid Services** under the Clinical Laboratory Improvements Amendments of 1988.

Meanwhile, since 2014, several proposed bills have surfaced in Congress that are intended to guide how clinical laboratory tests, including LDTs, are regulated. Each of these bills have different proponents and advocates from the *in vitro* (IVD) diagnostics industry and the clinical laboratory profession.

Lab directors and pathologists have long asserted that clinical lab tests are not medical devices and so are not subject to FDA regulations. However, lab industry leaders often fail to recognize the fraud and abuse problem. Also, they seldom offer recommendations on how federal regulators can curb fraud while still allowing ethical labs to offer clinically-useful tests. TDR

—Joseph Burns

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Anthem's Cuts in AP Fees Could Put Patients at Risk

Insurer's low payments might disrupt long-standing relationships between pathologists and physicians

CEO SUMMARY: Consultants who work with anatomic pathologists have several theories about why Anthem is enacting deep cuts of 50% to 70% for the professional component of many anatomic pathology services. While they have different ideas about what motivates the nation's second largest health insurer, they agree that such reductions in payments will have a harmful effect on patients and on the relationships referring physicians have with the anatomic pathologists in their communities.

WHAT HAPPENS AFTER A MAJOR INSURER SLASHES what it pays to physicians by 50% to 70%? Might patient referral relationships among physicians change for the worse? Would patients suffer as a consequence of their health insurer paying physicians just 30% of what they were paid in recent years?

Anthem, Inc., is about to learn the answers to those questions. Since late last year, the nation's second largest health insurer has cut what it pays for most anatomic pathology CPT codes by 50% to 70%. Given that Anthem serves 40-million members, such low reimbursement rates could cripple many anatomic pathology practices. *(See "Dermatologists Say Anthem Cuts Affect Patient Care," TDR, Aug. 12, and "Anthem Rolling Out New Pathology CPT Code Cuts," TDR, July 1.)*

In addition to forcing pathology groups to cut back on staff or go out of business, such low rates also could harm patients, according to physicians and consultants who advise anatomic pathology practices.

For example, one consultant who works with anatomic pathologists fears the deep cuts Anthem has made in certain AP codes will harm patients. Such harm will result from the disruption in the relationships that anatomic pathologists have with referring physicians, said the consultant, who asked not to be named.

Definitive Diagnosis

"The cuts in reimbursement may lead good local pathology groups to abandon their practices, thus leaving large labs as the only options for patient care," the consultant said. "The inherent difference between a large lab and a local, specialized lab is the definitive diagnosis you get from specialized labs. Some pathologists at large labs may take a wait-and-see approach to a potential case of cancer, which could compromise patients' long-term health."

In an e-mail to THE DARK REPORT, Anthem said it will not comment because its fee schedule is proprietary and confidential. Also, Anthem added that it follows the notice provisions defined in its provider agreements when it makes changes to the fee schedule.

Pathology consultants have different theories about why Anthem wants to make such deep cuts in payments, but they agreed that these reductions will

harm patients and pathologists' relationships with physicians.

Such harm may be particularly acute in the relationships that dermatologists have with referring physicians because disrupting these relationships harms patient care, the consultants said.

For example, dermatologists are concerned that Anthem's new payment rates for the professional component of AP services disrupt their ability to work with dermatopathologists. These professionals developed strong relationships over many years, they said.

Late last year, Anthem informed pathology groups in some states that it would cut what it pays for certain CPT codes in the 80000 series by 50% to 70%. These rates are much lower than what it had been paying. "I have heard from a number of pathologists who are distraught over the cuts that Anthem is imposing," said one consultant who has more than 30 years of experience working with pathologists. The consultant asked not to be named.

Loyal to Local Pathologists?

Asked why Anthem is slashing payments now, this consultant said large laboratories in Anthem's network may have complained to Anthem about how smaller and regional AP groups were retaining their referring physicians. Such loyalty to local pathology groups makes it difficult for the large labs to acquire the specimen volume from Anthem's patients because those patients' physicians prefer to send to the AP groups they have worked with for many years.

"When national labs struggle to win business away from local and regional pathologists, they will often pressure a health insurer to take steps to help them capture more physician referrals," he said. "After all, the national labs often discount their prices to as low as 30% of Medicare to win these managed care contracts. Now they need more case volume to keep their costs at break-even or better. That's why, for example, national labs would lobby Anthem to pressure its network physicians to steer that pathology work their way.

Going After Market Share

"In anatomic pathology, it's a fact of life that national labs will struggle to gain any business when trying to acquire new market in any city or large metropolitan area," he commented. "Local pathologists have a strong hold on their client physicians because they have worked closely with those physicians for many years. In addition, those referring physicians want to retain the long-standing relationships they have with local anatomic pathologists.

"After working with one pathology group over many years, a referring physician doesn't want to start over with anatomic pathologists they don't know," he explained. "Referring physicians—especially dermatologists but also gastroenterologists, genitourinary specialists, and others—rely on the familiarity they have with their pathologists. Also, they trust the accuracy they get from local pathology groups.

"Facing pressure from the large labs, Anthem's choices are limited," he added. "It could cut pathologists from its network, but it also could let its network pathologists self-select.

"Essentially, that's what's happening now. Anthem is telling pathologists, 'Here are your new contract rates. You can either take them or leave them,'" explained the consultant. "Anthem knows many in-network pathologists will drop out rather than accept such low reimbursement.

"In some cases, a pathology group may choose to go out of network," he said. "Or, if the pathologists are older and approaching retirement age, they'll simply sell to another group or close up shop.

"These developments are one way Anthem can make the large lab companies happy," he noted. "At the same time, Anthem benefits because it can now pay the low prices it wants to pay all across the country." TDR

—Joseph Burns

Pathology Update

Few Options for Pathology Groups Facing Anthem's Payment Cuts

FACED WITH DEEP CUTS in payment for anatomic pathology professional component services from **Anthem, Inc.**, pathologist have only a few options in how they can respond, according to consultants who work with AP groups.

"These are dire cuts to anatomic pathology reimbursement," said one consultant who asked not to be named. He suggested that small regional pathology labs have only three options: close or sell to competitor labs, cut back on staff to reduce costs, or drop out of Anthem's network.

Some Path Groups Will Close

"First, some pathology groups will be forced to close or sell," explained the consultant. "Second, some labs will cut costs by laying off staff. They'll start with the billing staff, but they also may need to let a pathologist go too. Third, some labs will just leave the Anthem network. In all three scenarios, Anthem members get hurt.

"In that second group, in which the labs cut costs, many pathology groups will struggle because cutting costs is difficult today," he added. "Equipment and reagents are more expensive than they've ever been.

"Also, it is increasingly expensive to hire pathologists coming out of residency," said the consultant. "The cost of running a pathology laboratory is always rising, but the reimbursement is going in the opposite direction."

For those labs forced to go out of network, Anthem will have a provider vacuum it needs to fill. "While the large national labs are good at what they do, they don't always have the local or regional relationships needed to deliver the fastest results to referring physicians," the consultant said. "To fill any holes in Anthem's network, some local and regional pathology labs may be able to contract with Anthem or subcontract with the large national labs, but that remains to be seen.

"Most patients are unaware of this, but referring physicians know they can get answers within 24 hours or even the same day from the anatomic pathologists in their town," he commented. "That's important in terms of providing quality patient care.

"Take the example of a referring physician who removes a suspicious lesion," he added. "That physician can get an accurate diagnosis the next day or maybe sooner from a local pathologist. I'm not sure the national laboratories can do that for all pathology services in all local communities."

When referring physicians and anatomic pathologists have close relationships that they've built up over many years, they can work together to improve patient care, the consultant said. Conversely, the opposite also is true, he added.

Quality Care vs. Patient Harm

"Those local relationships result in quality care," he said. "When a referring physician can ask his or her pathologist about a report the pathologist wrote, that alone can be the difference between quality care and potential harm to a patient.

"With large national labs, that personal relationship between the local physician and the local pathologist is diminished," he added. "When working with the national labs, referring physicians may need to call an 800 number and might not get a response the same day.

"Health plans don't understand that in some cases, their referring physicians

need to have an immediate and correct answer from the pathologist," he added. "In the case of a patient with cancer, that patient can't wait until his or her next office visit. After the biopsy specimen is collected, physicians and patients need to know within a day or two at the most."

Patients suffer when a pathology group is forced to drop out of an insurer's network or when it lays off a pathologist, because such disruption may lead to poor quality care. "Disruption in a long-standing relationship can increase the possibility of a patient getting a misdiagnosed cancer or a false negative," the consultant said. "Or, that general pathologist who is not a specialist may say the lesion or tumor is undeterminable and the patient should return in six months. In many cases, that might be bad advice.

Sub-specialist Pathologist

"Meanwhile, the specialized pathologist would identify that lesion or tumor exactly on day one, eliminating the need to wait for the next office visit," he added. "We know what can happen in six months: that cancer could spread."

Another consultant commented about the deep cuts Anthem is making. "Anthem has a view of pathologists that is unlike that of other insurers," said the second consultant who also asked not to be named. "For its billing purposes, Anthem has two types of pathologists. In one group are independent pathologists who play by the rules and don't try to bill outrageous amounts.

"The second group has tried to compete by commanding rates that are two, three, and four times higher for some anatomic pathology codes," the second consultant explained. "In my opinion, Anthem is targeting this second group. It's similar to what **Aetna** did four or five years ago when it trimmed its AP network to reduce costs by having members use in-network pathology groups or the large national labs whenever possible." TDR

—Joseph Burns

AP as Ancillary Service Is New Payer Strategy

ONE PATHOLOGY CONSULTANT HAS AN UNUSAL THEORY about Anthem's strategy to deeply cut anatomic pathology (AP) professional component (PC) payments while moving AP to an ancillary service.

"By categorizing the anatomic pathology professional component as an ancillary service, Anthem may believe it can cut what it pays for AP services," commented Mick Raich, CEO of **Vachette Pathology**, in Sylvania, Ohio. "When Anthem puts all AP labs under the ancillary services category, it doesn't have to pay the higher rates that it has been paying for the professional components of AP services.

"Next, by putting anatomic pathology professional groups under the ancillary fee schedule, Anthem then has a single fee schedule for all clinical laboratory and anatomic pathology services," noted Raich. "Doing so allows Anthem to pay whatever rate it chooses."

Bill to Curb Surprise Billing

In addition, Raich said, Anthem may hope Congress will pass a bill to limit surprise billing. "A national surprise billing law will have a benchmark rate for out-of-network care," Raich said. "Some health insurers may favor that law because they believe the benchmark out-of-network rate set by that law would be lower than what they're paying now for out-of-network care.

"If there is a low benchmark rate for out-of-network care and health insurers reset all of their contracts before the law goes into effect, what insurers pay for out-of-network care will be even lower than what they pay now," Raich explained. "If that happens, a federal surprise billing law could remove any option that any physicians—including anatomic pathologists—will have to negotiate for higher rates."

Arkansas Pathologist Faces 3 Manslaughter Charges

Officials say VA pathologist worked while under the influence, leading to multiple misdiagnoses

CEO SUMMARY: Federal prosecutors in Arkansas charged a former Veterans Administration pathologist with three counts of involuntary manslaughter and 28 other criminal counts related to his work at the Veterans Health Care System of the Ozarks. In the indictment, officials charged that the pathologist's misdiagnoses contributed to the deaths of 15 patients. The pathologist had been disciplined for alcohol abuse and had undergone addiction treatment, officials announced.

Federal authorities indicted an Arkansas pathologist last month on three counts of involuntary manslaughter, 12 counts of wire fraud, 12 counts of mail fraud, and four counts of making false statements related to his work for the **Department of Veterans Affairs**, officials announced.

Four days later, on Aug. 20, federal officials arrested pathologist Robert Morris Levy, age 53, after a year-long investigation, according to an announcement from Duane Kees, the U.S. Attorney for the Western District of Arkansas, and Michael Missal, Inspector General of the Department of Veterans Affairs.

Worked in Fayetteville

Levy had served as the Chief of Pathology and Laboratory Medical Services for the **Veterans Health Care System of the Ozarks**, in Fayetteville, Ark., from 2005 until he was fired in April 2018.

Charging a pathologist with three counts of involuntary manslaughter is a significant development for the pathology profession, because, as the *Washington Post* reported, it is extremely rare that federal officials will bring a criminal case against a pathologist. Most such cases involving misdiagnoses are addressed in civil court through malpractice claims, the *Post* reported.

However, the outcome of this case could be a precedent that gives other prosecutors the confidence that they can file criminal charges in cases where evidence shows that a pathologist's actions contributed to diagnostic errors that directly contributed to the death of one or more patients.

Review of 33,902 Cases

Levy had a history of alcohol abuse at the VA hospital over several years, the indictment showed. After he was fired, VA officials had outside pathologists re-examine 33,902 of Levy's cases in June 2018. During that review, the independent pathologists found more than 3,000 mistakes or misdiagnoses of patients at the VA hospital dating to 2005, and 30 of those misdiagnoses resulted in serious health risks to patients. *(See "Pathologist's Errors Associated with 12 Deaths at Arkansas VA," Feb. 25, 2018, and "Pathology Errors a Factor in 3 Deaths at VA Hospital," TDR, Oct. 1, 2018.)*

In the 16-page indictment, federal officials explained that Levy was suspected of being under the influence while at work in 2015, and was tested for drugs and alcohol and suspended in March 2016 and again in October 2017.

When he returned to work, Levy enrolled in a drugs- and alcohol-monitoring program but still managed to use drugs without being detected, despite being tested for drugs and alcohol 42 times over 20 months, the indictment said. By taking an intoxicating drug called 2-methyl-2-butanol (2M-2B), Levy avoided detection because 2M-2B is undetectable in routine drug and alcohol testing, the indictment said.

During this time, Levy reported that he had an error rate of 5% and was paid a financial bonus in 2016 and 2017 for having such a rate, when in fact his error rate was about 10%, the indictment said.

Involuntary Manslaughter

While VA officials told investigators his errors led to the deaths of 15 VA patients, Kees charged Levy with involuntary manslaughter in three VA patients' deaths, saying these were "the most serious and prosecutable cases," the *Washington Post* reported.

Levy's scheme to cover up years of drug and alcohol use on the job caused him to misread thousands of fluid and tissue samples of ill patients, the newspaper added. Over 12 years of work for the Veterans Health Care System of the Ozarks, Levy examined some 34,000 pathology slides from veterans, the *Post* wrote.

Levy's problems started in October 2015 when VA staff reported that he appeared to be intoxicated on duty, according to a 16-page superseding indictment that Kees filed. Levy denied the allegation when medical personnel questioned him at the time.

Six months later, in March 2016, Levy was working in the pathology laboratory when he was called to the radiology department to assist with a biopsy. "Levy appeared intoxicated when he arrived in the radiology department. He was asked to submit to a drug and alcohol test," the indictment states.

The VA and an independent medical facility tested his blood alcohol level and reported it was at 396.0 milligrams per deciliter (or 0.396 g/dl). As a result, the VA suspended his privileges to practice medicine. In July 2016, Levy voluntarily entered an in-patient alcohol treatment program, which he completed in October of the same year, the indictment said.

Monitoring Program

That fall, as Levy was preparing to return to work, he entered an impaired-physician monitoring program and agreed with the **Mississippi Physician Health Program** and the **Mississippi State Board of Medical Licensure** "to maintain sobriety to ensure his ability to practice medicine with reasonable skill and safety to patients," according to the indictment.

In this program, Levy agreed to "abstain completely from the use of ... alcohol and other mood-altering substances" and submit to random drug testing. He returned to work at the VA on Oct. 13, 2016.

In addition to onsite drug and alcohol testing at the VA, Levy also was tested randomly for drugs and alcohol through the impaired-physician monitoring program. "The testing protocol for the impaired-physician monitoring program required Levy to randomly provide urine specimens and blood samples," the indictment said.

Impaired Doctor Monitoring

From November 2016 through July 3, 2018, Levy provided 42 urine specimens or blood samples that were collected and tested pursuant to the impaired physician monitoring program. All were reported negative for the presence of drugs or alcohol, the indictment said.

"On 12 occasions beginning in June 2017 and continuing through 2018, while

Indictment of Arkansas Pathologist Explains Three Counts of Involuntary Manslaughter

IN THE INDICTMENT OF ROBERT MORRIS LEVY, MD, the former pathologist for the Department of Veterans Affairs who was indicted and arrested last month, federal officials explained the three counts of involuntary manslaughter.

From about Feb. 4, 2014, to about July 26, 2014, while working as a pathologist at the Veterans Health Care System of the Ozarks, in Fayetteville, Ark., Levy caused the death of a patient identified as JRG. In the indictment, federal officials said, "…on or about Feb. 4, 2014, Levy entered an incorrect and misleading diagnosis of diffuse large B cell lymphoma in JRG's medical record and falsified an entry in JRG's medical record that stated a second pathologist concurred with the diagnosis of diffuse large B cell lymphoma."

Then on Feb. 10, 2014, Levy changed the incorrect and misleading diagnosis of diffuse large B cell lymphoma in JRG's medical record to another incorrect and misleading diagnosis, namely adenocarcinoma, the indictment said.

In fact, JRG's tissue biopsy did not show that the patient had either type of cancer, the indictment said. JRG was treated for a type of cancer the patient did not have, the patient did not respond to the wrong treatment, and JRG died of small cell carcinoma in July 2014, the indictment added.

In the second case of involuntary manslaughter, the indictment said that from Sept. 22, 2014, to about Sept. 13, 2015, Levy caused the death of a patient identified as JDQ by entering an incorrect diagnosis of small cell carcinoma and a false entry in JDQ's medical record that a second pathologist concurred with the diagnosis of small cell carcinoma. In fact, JDQ's tissue biopsy revealed squamous cell carcinoma and Levy knew that a second pathologist did not concur with the diagnosis of small cell carcinoma, the indictment said. On about Sept. 13, 2015, JDQ died of widely-spread squamous cell carcinoma.

In the third case of involuntary manslaughter, the indictment said, Levy caused the death of a patient identified as DRM by entering an incorrect diagnosis into DRM's medical record stating that the patient's prostatic tissue was benign. DRM then relied on pathologist Levy's diagnosis that his biopsy was negative for cancer, when in fact, the patient's prostatic tissue was obviously cancerous, the indictment said. DRM did not receive timely treatment and died of metastatic prostate cancer on about April 28, 2016.

Levy was contractually obligated to submit to random drug and alcohol screens, Levy purchased for personal consumption 2-methyl-2-butanol (2M-2B), a chemical substance that enables a person to achieve a state of intoxication but is not detectable in routine drug and alcohol testing methodology," Kees said when he announced the indictment and arrest.

In October 2017, Levy's colleagues reported that he appeared to be intoxicated on duty. When VA officials tested Levy's urine and blood, no drugs or alcohol were detected.

In 2016 and 2017, the VA paid Levy an annual salary of $225,000, contributed to his retirement account, paid for other employee benefits, and gave him financial performance bonuses. The performance bonuses were due, in part, to Levy's reports to the VA that his clinical error rate was less than 5%. In fact, almost 10% of his diagnoses involved clinical errors, the indictment said.

Reckless Homicide Charges Against a Pathologist Were Considered in Earlier Case

THERE IS AT LEAST ONE OTHER CASE WHERE A PATHOLOGIST faced the possibility of a criminal charge for homicide or manslaughter as a result of actions linked to diagnostic errors that directly contributed to one or more patient deaths.

That case made headlines in 1995, when a district attorney in Wisconsin County, a suburban area to Milwaukee, filed two counts of reckless homicide against **Chem-Bio Corporation**, a clinical laboratory company located in Oak Creek, Wisconsin.

After two female patients, aged 29 and 40, died of cervical cancer, despite having had annual Pap smear tests, an investigation of Pap testing practices at Chem-Bio was conducted. It was determined that pathologist Robert Lipo, MD, the owner and laboratory director, and cytotechnologist June Fricano, (who read the cases of those two patients), failed to follow established practices and laboratory regulations.

It was also learned that Fricano was paid $2 per Pap slide and, during one year, had screened more than 48,000 Pap slides. That same year, she was paid $96,000 from Chem-Bio, at a time when the average cytotech made about $33,000 per year.

One news story quoted a Chem-Bio co-worker of Fricano's as describing how Fricano circumvented the random selection of Pap slides for quality control review by using the number 2 when it was the last digit on the slide's accession number. This same cytotech told a reporter that, in 1991, at the request of a doctor, she pulled a Pap slide from 1987 and described it as having "almost no normal cells on it," even though it was orginally reported as normal.

Milwaukee County District Attorney Michael McCann presented the findings of this investigation to a Milwaukee inquest jury. As reported by the *DePaul Journal of Healthcare Law*, "The inquest jury came back with an unprecedented recommendation: charge Chem-Bio, [cytotechnologist] June Fricano, and Robert Lipo, the head of the laboratory, with reckless homicide. McCann decided against prosecuting Fricano and Lipo. 'There was no criminal intent on any individual's part,' McCann stated."

Instead, McCann chose to charge Chem-Bio with two counts of reckless homicide. Chem-Bio settled that case in December, 1995. It pleaded no contest to the charges and paid the maximum legally allowable fine of $20,000. In exchange for deferring prosecution for six years for the reckless homicide charges, Lipo and Fricano each agreed to a settlement that limited what responsibilities they could perform in clinical laboratories.

The indictment showed that on 12 occasions from June 30, 2017, through June 13, 2018, Levy used the online auction site **Ebay.com** and **Amazon Marketplace** to buy 500 milliliters of 2M-2B from **Chemsavers Inc**. The purchases resulted in 12 counts of wire fraud and 12 counts of mail fraud.

In addition to mail and wire fraud, the indictment explained that Levy made false statements on four occasions. The first false statement was made on June 14, 2017, when Levy entered into the medical record of a patient identified as WG that a second pathologist concurred with his diagnosis of non-small-cell carcinoma when the second pathologist had not yet reviewed the case, the indictment said.

Levy made the other three false statements in June and July 2018. One false statement was on June 4, 2018, during a VA hearing, one on July 20, 2018, to a VA investigator, and one on July 23, 2018, to the same VA investigator, as described in the indictment. **TDR**

—Joseph Burns

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OIG Finds 120-Day Delays at Memphis VA Path Lab

In its report, OIG found that delays in review of pathology specimens affected 123 patients

CEO SUMMARY: Last year, Veterans Administration officials received an anonymous complaint about delays in laboratory specimen processing and results at the Memphis VA Medical Center may have harmed patients and led to a patient death. Following an investigation, the VA's Office of Inspector General issued a report last month. It determined that a staff shortage contributed to the delays and that only 62% of the full-time positions authorized for the pathology lab were filled.

A VETERANS ADMINISTRATION REPORT showed delays of as long as 120 days or more in the processing of histology tissue specimens in the **Pathology and Laboratory Medicine Service** (PLMS) at the **Memphis VA Medical Center**.

Late last month, the federal Veterans Administration's Office of Inspector General (OIG) found that the PLMS was responsible for delays in laboratory specimen processing which affected 123 cases. However, after assessing the electronic health records of 136 patients, the report found no evidence of patient harm.

10-Day TAT in 2017

Turnaround times in the pathology laboratory were as long as 10 to 12 days in January and February of 2017. This was far from the facility's goal of two-day turnaround for surgical pathology cases.

The delays resulted from severe staffing shortages among pathologists, histotechs, medical technicians, and other positions, and that the service had almost two vacant positions (1.8 full-time equivalents) for pathologists during the period under review. There were also deficiencies in the PLMS' quality management and surgical pathology quality assessment.

The OIG team could not confirm a consistent process was in place for quality management. In addition, documentation was missing for initial employee orientation, six-month competency assessments, and annual competency reviews.

The OIG concluded that a shortage of staff was a contributing factor. This development follows closely after a peer-reviewed medical journal published a study that showed the number of pathologists in the United States had declined by 17.5% from 2007 through 2017. *(See "JAMA Study: 17% Fewer Pathologists in U.S. Since 2007," TDR, June 10, 2019.)*

The OIG's report is remarkably understated in its assessment of the problems in the PLMS. In several places, for example, the report showed that the PLMS could not produce reports the OIG needed to assess reasons for the pathology lab's delays.

The report's conclusion showed that, for example, "facility leaders were unable to produce evidence that processes to pre-

vent delays had been incorporated into a PLMS policy."

It also included this statement: "Because the OIG team could not verify the methodology used to identify patients affected by surgical pathology processing delays, the OIG was unable to determine if facility leaders completed a comprehensive assessment of the processing delays and any impact on affected patients."

Staff shortage was one reason for the delays. When the OIG team visited the Memphis VA in November 2018, the PLMS was approved to have almost 80 (79.8 full-time equivalent) employees. But at the time, PLMS had almost 30 (29.8) vacant full-time positions. To fill the gap, PLMS used contract employees for frontline staff positions, including medical technicians and histopathologists, the chief of staff said.

38% Vacancy Rate

Of the 30 full-time positions vacant in October 2018, the PLMS staff at the Memphis VA Medical Center was short 1.8 pathologists, 10 medical technicians, eight medical technologists, two lead medical technicians, and two transcription program assistants—some of the most important staff in a pathology lab.

Also, there was one vacancy in each of the following positions: pathologist specialist, program assistant, lab information manager, supervisory medical technician, supervisory histopathology technician, and histopathology technician.

It's no surprise then that the OIG found that inadequate staffing affected the ability of the PLMS to deliver specimens for processing in a timely manner. The pathology laboratory at the Memphis VA was operating with just 62% of the authorized and budgeted staff positions.

The report concluded by saying that in January and February 2017, surgical pathology processing delays were attributed to a transcription software issue, shortages of facility pathologists, and relying on pathology residents from the **University of Tennessee** for initial processing of tissue specimens.

The report also concluded that while PLMS staff improved TAT for surgical pathology specimens done onsite, the laboratory's leaders were unable to show that that processes to prevent delays had been implemented.

An Anonymous Complaint

Last year, the VA OIG got an anonymous complaint alleging that the previous chief of the PLMS service at the Memphis VA was responsible for delays in laboratory specimen processing that resulted in patient harm and possibly death due to delayed reporting of pathology results.

For the report issued last month, the OIG said it reviewed the electronic health records of 136 patients and found no adverse clinical outcomes from the delays in processing pathology specimens. The OIG did, however, recommend eight steps the lab and pathology service could implement to improve operations.

To assess the timeliness of specimen TAT, the OIG team reviewed surgical pathology reports for the period from January 2017 through September 2018 and found that the facility decreased TAT in that time from 10 days in January 2017 and 12 days in February 2017 to two delays from March through September 2018.

Inadequate Lab Staffing

Although OIG investigators did not uncover an example of patient harm attributable to specimen processing delays, the report did not comment on the consequences of the lab's staffing shortage. Most experienced pathologists and clinical lab administrators know that, with just 62% of authorized staff positions filled, there is the potential for many essential tasks to either not be performed, or to be performed poorly. They would assess the inadequate staffing at this lab site to be a risk factor that could contribute to patient harm in the future. **TDR**

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Two more clinical laboratory organizations that used **American Medical Collection Agency** (AMCA) to handle their lab test claims announced in July that their patients' data was breached. **Inform Diagnostics** of Irving, Texas, disclosed that the data of 173,716 patients was compromised. Within days of that announcement, **CompuNet Clinical Laboratories** of Moraine, Ohio, stated that about 110,000 of its patients had data exposed by the data breach at AMCA. Both lab companies said they have stopped doing business with AMCA.

MORE ON: *Data Breach*

Among the first laboratory companies to publicly disclose that their patients' data had been compromised by a breach at AMCA were **BioReference Laboratories**, **LabCorp**, and **Quest Diagnostics**. *(See TDR, June 10, 2019.)* According to the *HIPAA Journal*, AMCA has told 20 or more companies that their patient data have been exposed by the breach, and at least 24,390,307 patients were notified that their data was compromised.

TRANSITIONS

• The *Indiana Business Journal* reported that Jack J. Philips, currently CEO of **Roche Diagnostics** North America, is leaving the company as of August 31. He will become CEO of **Accelerate Diagnostics**, of Tucson, Ariz. Philips previously held positions at **Ventana Medical Systems** and **Chiron Diagnostics**.

• Pathologist Donald A.B. Lindberg, MD, FACMI, 85 years old, died on August 17, 2019, at his home in Columbia, Missouri. Before retiring, he was the Director of the **National Library of Medicine** for more than 30 years. Lindberg is recognized as pioneering the application of computer technology in healthcare beginning in 1960 when he was at the **University of Missouri**.

• **Ortho-Clinical Diagnostics** announced the appointment of Chris Smith as its new Chief Executive Officer, effective Sept. 9. Smith formerly held executive positions at **Cochlear Limited**, **Warburg Pincus**, and **Gyrus Group Plc**.

• Ortho-Clinical Diagnostics also stated that Robert Yates, currently OCD's President, will step down from that role and continue to serve on the company's board as non-Executive Chairman. Yates came to OCD in 2014 and previously served at **Merck KGaA's EMD/Merck Millipore** division, and **Roche Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 23, 2019.

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