G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

May 2016

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Drug Testing Enforcement Cases Lead to Costly Settlements and Convictions

Pain management and drug abuse have received significant media attention and federal funding devoted to stopping an opioid epidemic. Health care fraud enforcement agencies are also focused on the providers who profit from unnecessary testing related to pain management and drug abuse treatment programs.

Recent health care fraud enforcement cases involving diagnostic professionals performing drug testing for Medicare beneficiaries have resulted in a multi-million dollar settlement and the conviction of two lab professionals. "It's unconscionable that anyone would exploit this epidemic to enrich themselves on such a massive scale," said Virginia Attorney General Mark R. Herring in a press release announcing the convictions in one fraud case.

Two Tennessee lab professionals were convicted April 7, 2016, of federal conspiracy and health care fraud charges relating to urine drug screening tests. The government alleged that Beth Palin, 49, and Joseph D. Webb, 55, who owned Bristol Labs, billed Medicare, Medic-

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Labs with International Aspirations Need to Focus on FCPA Compliance Challenges

Laboratories are very familiar with the Anti-Kickback Statute and its prohibitions against payments to induce referrals. Laboratories and diagnostics companies looking at global opportunities should be similarly mindful of recent developments relating to enforcement of the Foreign Corrupt Practices Act (FCPA), which also applies to payments intended to generate business. The FCPA prohibits payments to foreign government officials to obtain or retain business, or direct business to any person—i.e., bribes. The anti-bribery provision applies not just to U.S. persons but also to foreign entities who cause such improper payments to occur within U.S. territory.

In health care it is often pharmaceutical companies that have run afoul of the FCPA. But recently, it was a point-of-care diagnostic test maker in the news in connection with FCPA allegations. Alere disclosed in a Securities and Exchange Commission Form 8-K filing that it received a grand jury subpoena in March from the United States Department of

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Labs with International Aspirations Need to Focus on FCPA Compliance Challenges, *from page 1*

Justice "requiring the production of documents relating to, among other things, sales, sales practices and dealings with third-parties (including distributors and foreign governmental officials) in Africa, Asia and Latin America and other matters related to the U.S. Foreign Corrupt Practices Act." There could be more such investigations in the future for the diagnostics industry. *National Intelligence Report*'s sister publication, *Laboratory Industry Report* recently highlighted the globalization of the U.S. diagnostics industry, with foreign countries seeking to gain a foothold in the U.S. market and U.S. companies taking note of foreign opportunities. (See "Inside the Lab Industry," *Laboratory Industry Report*, 3/17/16, p. 4).

At the same time, the Department of Justice (DOJ) is ramping up enforcement of this law, issuing a memorandum April 5, 2016, titled "The Fraud Section's Foreign Corrupt Practices Act Enforcement Plan and Guidance"—outlining three steps of "enhanced FCPA enforcement strategy."

Step one involves "intensifying its investigative and prosecutorial efforts" by adding new resources such as 10 new prosecutors for the FCPA Unit (a 50 per cent increase in that unit), and three new squads of agents focused on FCPA investigations and prosecutions. Step two involves strengthened U.S. "coordination with foreign counterparts in the effort to hold corrupt individuals and companies accountable." Such coordination includes sharing leads, documents and witnesses. The third step is a one-year pilot program in the Fraud Section's FCPA Unit intended to "promote greater accountability" by encouraging self-disclosure, cooperation with Fraud Section investigations, and remediation of compliance programs.

Assistant Attorney General Leslie R. Caldwell, with the DOJ Criminal Division, explained in a statement that the pilot program promotes transparency by letting companies know what they can expect in FCPA enforcement, what penalties will result from certain conduct, and it "enable[s] companies to make more rational decisions when they learn of foreign corrupt activity by their agents and employees." The April memo makes clear: "Nothing in the Guidance is intended to suggest that the government can require business organizations to voluntarily self-disclose, cooperate, or remediate. Companies remain free to reject these options and forego the credit available under the pilot program." However, Caldwell cautioned that "[i]f a company opts not to self-disclose, it should do so understanding that in any eventual investigation that decision will result in a significantly different outcome than if the company had voluntarily disclosed the conduct to us and cooperated in our investigation."

The DOJ explains that this new guidance supplements the Principles of Federal Prosecution of Business Organizations (known as the USAM Principles)—which address whether and what type of criminal disposition against a corporation is appropriate—and the U.S. Sentencing Guidelines (USSG) which provide for reduced fines and penalties for organizations that voluntarily disclose misconduct and cooperate in investigations. The DOJ's FCPA guidance also explains when additional credit can be granted in FCPA cases beyond credit provided under the USSG. It applies to all FCPA cases in which companies self-disclose or cooperate during the pilot period—even if the case lasts after the pilot ends.

But to benefit from that credit, an organization must meet the following three requirements:

1. **Voluntary self-disclosure of FCPA misconduct.** The disclosure must be made before an "imminent threat of disclosure or government investigation" and within a "reasonably prompt time after becoming aware of the offense" and must include all relevant facts regarding the conduct and the individuals involved.
2. **Full cooperation.** This includes compliance with the Yates memo's principles requiring disclosure of facts that identify culpable officers, employees or agents of the corporation. The FCPA guidance also emphasizes the need for cooperation to be "proactive … rather than reactive"—meaning the company must disclose information that is not even asked for and must "identify opportunities for the government to obtain relevant evidence" the company doesn't have or the government doesn't know about. Note too that this requires disclosure of overseas documents unless foreign privacy law prevents such disclosure.
3. **Remediation.** Remediation requires appropriate discipline of employees who are identified as responsible for misconduct and implementation of an effective compliance and ethics program, including a culture of compliance, an independent compliance function, sufficient resources, involvement of experienced compliance personnel, compliance programs that match results of risk assessments, auditing of compliance programs, and compensation and promotion of compliance staff comparable to other employees. The corporation must also take any other steps necessary to demonstrate "recognition of the seriousness of the corporation's misconduct," accept responsibility and reduce risk of reoccurrence.

The credit that may be gained by satisfying voluntary self-disclosure requirements, including compliance with the Yates memo and the USAM Principles, could include up to 50 percent reduction "off the bottom end of the Sentencing Guidelines fine range" and "generally should not require the appointment of a monitor" if the company already has an effective compliance program. Additionally, the Fraud Section's FCPA Unit may consider declination of prosecution—but, the government will also consider the seriousness of the offense, involvement of the company's executive management, significance of profit to the company from the conduct (in relation to company size), prior noncompliance, and prior resolution of a matter with the DOJ within the past five years.

An entity that fails to self-disclose but does satisfy requirements to cooperate and remediate can still receive limited credit under the pilot program. However, the guidance warns "[s]uch credit will be markedly less than that afforded to companies that do self-disclose wrongdoing." At most, that will be a 25 percent reduction from the "bottom of the Sentencing Guidelines fine range."

Takeaway: Laboratories seeking to enter the global market need to heed the DOJ's stepped up enforcement of the FCPA; such enforcement also re-emphasizes the government's focus on pursuing liability for culpable individuals within the corporations found to have violated the law.

Nearly Half of Top 10 Patient Safety Concerns Relevant to Labs

Four of the top 10 patient safety concerns, compiled from reports of more than 1.2 million safety events, literature review and expert opinion, have relevance for laboratories and diagnostics. ECRI Institute's third annual *Top 10 Patient Safety Concerns for Healthcare Organizations 2016* includes "real things that are happening," stated Associ-

ate Director for the ECRI Institute PSO, Catherine Pusey, RN, MBA, in the executive summary. They aren't the most frequently cited or the most severe issues, added Bill Marella, MBA, MMI, ECRI's executive director, PSO operations and analytics. "We're trying to pick out the things that are relatively novel or that are not necessarily new but are manifesting themselves in a new way because of changes in the healthcare system."

Labs will find most relevant the safety issue appearing at number five on ECRI's list: Inadequate Test-Result Reporting and Follow-up. Factors that affect test reporting safety issues included inadequate communication among providers and failure to follow up with and by patients on test results and their health implications.

There are several other items that are also of relevance to laboratories on the list. The number one safety concern cited was "Health IT configurations and organizational workflows that do not support each other"—meaning that operationally, people don't adjust to new IT systems. This disconnect affects communication and prevents up-to-date sharing of information about patients including, for example, lab test results. This is an issue very relevant to laboratories who utilize IT systems to communicate with referring providers regarding test orders and test results.

"Action is needed now to avoid an antibiotic apocalypse."

— Sharon Bradley, RN, CIC, ECRI Institute

The second item on the list is patient identification errors—which ECRI notes have "broad implications" and "serious consequences." *G2 Compliance Advisor (GCA)* has previously highlighted the importance of the lab's role in patient identification (see *GCA*, March, 2016, p. 3). Tejal Gandhi, M.D., president and CEO of the National Patient Safety Foundation (NPSF) told sister publication *National Intelligence Report* that labs need to look at internal processes that could lead to a potential breakdown in patient identification. For example, they need to consider how certain they are that results are received by providers and identify communication gaps so they can make processes more reliable. Additionally, the College of Healthcare Information Management Executives (CHIME) has launched a National Patient ID Challenge to find solutions to patient identification errors. CHIME pointed out that the error rate in matching patients to their records is usually 10 to 20% within a healthcare system and can rise to 50 to 60% when organizations exchange data through the care continuum.

Two issues at the bottom of the top 10 should resonate for labs as well: inadequate antimicrobial stewardship (ninth on the list of top 10 safety issues) and failure to embrace a culture of safety (10th). Antibiotic resistance is a national concern receiving not just media attention but significant federal funding. ECRI's report raises the alarm stating "Action is needed now to avoid an antibiotic apocalypse," added Sharon Bradley, RN, CIC, ECRI Institute's senior infection prevention analyst, in ECRI's executive summary. Diagnostics play a key role in the fight against antibiotic resistance. In fact, the federal government's Combating Antibiotic-Resistant Bacteria (CARB) National Action Plan includes efforts to "advance the development of diagnostics to detect antimicrobial resistance."

Finally, all health care organizations including laboratories, should be concerned about a culture of safety. "[E]mbracing a culture of safety is the foundation for mitigating any of the concerns on the Top 10 list," according to ECRI Institute patient safety analyst and consultant, Mary Beth Mitchell, MSN, RN, CPHQ, CCM, SSBB, who also advised in the report that leadership must set the tone by publicly embracing patient safety.

Takeaway: Laboratories need to consider top patient safety concerns for health care organizations and how they can contribute to solving these safety issues.

After the Whistle Blows: Disciplining Whistleblowers without Committing Retaliation

The False Claims Act (FCA) has become the federal government's primary weapon in combating fraud and abuse. Paradoxically, though, most FCA cases are initiated not by the government but private individuals filing whistleblower claims on its behalf. So called "*qui tam*" suits accounted for $14.961 billion of the $16.756 billion the government recovered from health care providers under the FCA since 2009, according to the U.S. Department of Justice. (See Box on page 8 for year-by-year totals). Just who are these whistleblowers?

In most cases, they're employees who believe their company has defrauded the government and want to do right. Another motivation: If fraud is found, whistleblowers get a share of the money recovered. But while winning a *qui tam* suit can net whistleblowers a big payday, bringing one can cost them their job, professional reputation and peace of mind.

The Retaliation Conundrum

The anti-retaliation provisions of the FCA are designed to ensure that employees don't get fired or suffer other retaliation for whistleblowing. Nobody would deny that whistleblowers need this protection. But protection from retaliation doesn't give whistleblowers blanket immunity from discipline or bar labs from legitimately enforcing their work rules and policies.

As a lab manager, you must be prepared to deal with employees who remain at their jobs after blowing the whistle without crossing the line between legitimate discipline and illegal retaliation. This article will explain what you need to know about FCA anti-retaliation requirements to meet that challenge.

The Four Things Employees Must Show to Prove Retaliation

> **Anti-Retaliation Rule:** Any employee, contractor, or agent shall be entitled to all relief necessary to make [them] whole, if [they are] discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent, or associated others in furtherance of an action under this section or other efforts to stop one or more violations of this subchapter. (FCA, 31 U.S.C. Section 3730(h))

Employees bear the burden of proof in retaliation cases. To meet it, there are four things an employee must prove. You can defend your lab against a retaliation charge by disproving any one of those elements. So let's take a close look at each one.

#1. The Employee Engaged in Protected Activity

First, employees must show that they engaged in activities protected against retaliation. The FCA defines protected activities broadly to include *either:* i. "lawful acts . . . in furtherance of" a *qui tam* action; *or*, ii. "other efforts to stop one or more" FCA violations.

"Lawful acts": The word "lawful" is no throwaway. It means that it's not retaliation to discipline employees for doing something illegal, such as using protected patient records in violation of HIPAA to support their *qui tam* claims.

"Other efforts": The "other efforts" language, which was added to the FCA in 2009, means employees don't actually have to file a *qui tam* lawsuit to be protected from retaliation. "Other efforts" may include:

- Collecting information about potential fraud and abuse even if the employee hasn't put all of the pieces of the puzzle together yet;
- Reporting suspected misconduct to supervisors or lab officials; and
- Opposing or refusing to participate in attempts to submit or get paid for false or fraudulent claims.

An employee's belief that the lab has committed an FCA violation need not be correct. As long as the belief is sincere, held in good faith and reasonable, the employee is protected.

You Make The Call

Situation: A patient transport company provides free hot dogs and burgers at Holzer Health Systems physician picnics. A Holzer compliance officer complains to the CEO that the arrangement is an illegal kickback in exchange for patient referrals. Although well-intentioned, as a compliance officer, she should realize that anti-kickback laws don't apply to gifts of nominal value like hamburgers and hot dogs.

Question: Did Holzer commit retaliation by firing the compliance officer?

Answer: No. Although the compliance officer's belief was sincere and in good faith, it was unreasonable and "manifestly inconsistent with applicable law," according to the U.S. Court of Appeals for the Sixth Circuit.

#2. You Knew About the Protected Activity

Having proven that they engaged in protected activity, employees must show that the lab knew of the activity. Employees can meet this burden by showing that a lab manager, supervisor or other official or agent was aware of the protected activity.

#3. You Took Adverse Action against the Employee

Next, employees must show that the lab took an adverse action banned by the FCA. Such actions include:

- Termination;
- Demotion;
- Suspension;
- Threat;
- Harassment; or
- Other discrimination in the terms and conditions of employment.

#4. You Took Adverse Action *Because of* the Protected Activity

The mere fact that employees received discipline or adverse treatment after engaging in protected activity isn't enough to prove they suffered retaliation. Maybe the employees *deserved* to be disciplined for infractions unrelated to their whistleblowing activity. After all, why should a nurse be able to avoid the consequences of showing up for work drunk on Wednesday simply because she happened to have filed a *qui tam* suit on Monday?

How can you tell whether there's a causal connection between protected whistleblowing activity and the adverse action? Most courts use a burden-shifting approach:

- *Phase 1:* The employee must make what's called a "prima facie" case showing the lab committed retaliation, essentially by proving the first three elements;
- *Phase 2:* The burden then shifts to the lab to show a legitimate, non-retaliatory reason for the action;
- *Phase 3:* The burden then shifts back to the employee to show that the legitimate reason was a pretext for the action.

Although it's a case-by-case determination, timing is often a key factor in determining cause. Accordingly, terminations, demotions, etc. are most likely to be deemed retaliatory when they occur within a month or two of the protected activity (or, more precisely, the lab's knowledge of the protected activity). Conversely, adverse actions against whistleblowers are easier to justify as non-retaliatory when they occur a year or more after the protected activity or are the culmination of a disciplinary process put into motion *before* the activity.

Example: A lab fires a billing manager a month after she files a *qui tam* suit. The timing looks highly suspicious. But the lab may be able to overcome that by showing that the billing manager had been on probation for performance issues for a year and was fired for violating the terms of a last chance agreement signed weeks before she engaged in whistleblowing activity.

Other factors affecting determination of causation may include:

- A history of bad blood between the lab and employee;
- The seriousness of the alleged offense;
- Whether proper disciplinary procedure is followed; and
- The credibility (and likeability) of the parties and witnesses involved.

Five Ways to Protect Your Lab

Dealing with employees who remain at their jobs after blowing the whistle is tricky. Whistleblowers are likely to harbor resentment toward your lab and feel like there's a target on their back. So it's critical for all lab personnel to be sensitive of the situation and avoid engaging in needless provocation that the whistleblower may construe as retaliation. At the same time, labs need to ensure that employees follow rules and do their jobs even after they blow the whistle. There are five things you can do to strike the right balance.

#1. Implement a Non-Retaliation Policy

First, you need a clearly worded non-retaliation policy. Although it can't be one-size-fits-all, a standard non-retaliation policy should:

- State your lab's commitment to comply with all fraud and abuse and other applicable laws;
- Remind employees that they won't suffer retaliation for engaging in protected activity;
- Define the protected activities employees can engage in without retaliation;
- Define retaliation;
- Require supervisors and managers to follow an open-door policy and refrain from retaliation; and
- State that anybody who commits retaliation will be disciplined up to and including termination.

#2. Build Awareness of Your Non-Retaliation Policy

A non-retaliation policy, no matter how eloquently worded, won't do much good if nobody believes in it. You must build awareness and remind employees of the policy's existence. Above all, you must strictly adhere to it in the event employees do engage in whistleblowing activity.

#3. Limit Employees' Access to Lab Information

Be careful about letting whistleblowers take documents home or giving them full access to your protected information. *Explanation:* The ban on retaliation protects lawful activity and

doesn't give whistleblowers the right to misappropriate your private and confidential records to support their *qui tam* claims. This includes patient medical records whose use or disclosure would violate HIPAA as well as your lab's trade secrets or proprietary business information.

You Make The Call

Situation: The billing manager of a private physician practice secretly downloads confidential patient records and proprietary information for use as evidence to support her false claims *qui tam* suit.

Question: Can the practice discipline the billing manager for violating its confidentiality?

Answer: Yes. The protection against retaliation doesn't apply in this case because illegally misappropriating confidential records is not protected activity under the FCA.

Implementation Tip: Although HIPAA protection is automatic, your right to protect proprietary information may depend on whether the employee signs a clear and enforceable confidentiality agreement. *Caveat:* A confidential *policy*, e.g., in an HR Handbook, that the employee doesn't actually sign may be less easy to enforce since it's not a contract.

#4. Follow Your Normal Disciplinary Procedures

Although the ban on retaliation doesn't take discipline completely off the table, it makes it imperative that any discipline you do impose on whistleblowers be for legitimate reasons not related to protected whistleblowing activity. Also keep in mind that courts consider not just the reason for discipline but the process you use to mete it out. So scrupulously follow your normal disciplinary procedures the way you would when disciplining any other employee. Remember that any inconsistencies in the process will count as evidence that the whistleblower was singled out for retaliatory discipline.

#5. Keep Detailed Disciplinary Records

Last but not least, keep detailed records—memos, letters, notes from supervisors, photographs, etc.—documenting the disciplinary actions you take, your reasons for taking them and the procedures you followed in putting those decisions into effect.

Final Caveat: Don't Count on a Release to Protect You

Employees who complain about fraud and abuse may decide to resign voluntarily. If the employee hasn't yet filed a *qui tam* suit, it may be tempting to ask her to sign a written release promising not to sue your lab in exchange for a severance package. But courts consider releases to be a violation of public policy and won't enforce them. Exception: A release may be enforceable if the lab discloses the employee's allegations to the government. Explanation: The disclosure neutralizes the public policy argument because it makes the government aware of the allegations. G2

False Claims Act Damages Recovered in *Qui Tam* Cases against Health Care Providers Since 2009 (In billions of dollars)

Year	*Qui Tam* Recovery against Health Care Providers	Total Recovery against Health Care Providers
2009	$1.394	$1.632
2010	$1.969	$2.508
2011	$2.271	$2.449
2012	$2.541	$3.098
2013	$2.642	$2.703
2014	$2.313	$2.401
2015	$1.831	$1.965
Total	**$14.961**	**$16.756**

U.S. Department of Justice

Drug Testing Enforcement Cases Lead to Costly Settlements and Convictions, *from page 1*

aid, TennCare and other insurers for medically unnecessary drug tests which were not used by the treating physician to determine patient care.

> ***"This settlement is one of many that are sending a strong message to the lab industry that they need to clean up their act."***
>
> **—Derrick L. Jackson**

According to the U.S. Attorney, the two lab professionals worked with a physician who set up a "purported" substance abuse treatment program adjacent to their lab in Virginia. The physician's program involved only medication-assisted treatment, prescribing Suboxone, and required weekly drug testing for his patients, 100 percent of which the government said he referred to Bristol Labs. Insured patients were prescribed expensive drug screening tests (automated screens), which were billed to Medicare and Medicaid and other insurers, and paid nothing out of pocket, while uninsured, self-pay patients were prescribed a $25 dipstick drug screen. The government also alleged that Palin and Webb set up their own addiction practice with a similar test ordering procedure. The government alleged the testing scheme led to more than $14 million in medically unnecessary drug tests.

"Clinical labs play a critical role in providing care for people on Medicare," said Special Agent in Charge Nick DiGiulio, of the Office of Inspector General. "Lab professionals who aim to get rich quick by cheating patients and taxpayers, as in this case, can expect to pay a high price for their crimes."

In another case, PremierTox 2.0, Inc. settled for $2.5 million False Claims allegations relating to urine drug screenings in Tennessee and Kentucky. The government alleged three types of conduct gave rise to false claims: 1) PremierTox (doing business in Tennessee under the name Nexus) gave discounts on drug screen tests for uninsured patients in exchange for referrals of Medicare or TennCare covered patients; 2) PremierTox/Nexus submitted Medicare and TennCare claims for lab tests that were not medically reasonable and necessary; and 3) PremierTox provided Kentucky providers with free point of care testing cups for using its services. The settlement resolves two separate cases against PremierTox/Nexus brought by whistleblowers in Kentucky and Tennessee. Unlike a conviction this settlement means the allegations were not proven in court and no liability was determined.

"Medically unnecessary lab tests and financial incentives from labs to doctors in exchange for referrals are costing the taxpayers millions of dollars," said Derrick L. Jackson, Special Agent in Charge for the Office of Inspector General in Atlanta. "This settlement is one of many that are sending a strong message to the lab industry that they need to clean up their act."

Takeaway: Diagnostic professionals billing for drug screening tests relating to pain management and substance abuse treatment face government scrutiny.

Theranos Faces New Challenges and Increasing Federal Scrutiny

Theranos continues to face challenges concerning its Newark, Calif., laboratory as its initial response to Centers for Medicare & Medicaid Services (CMS) failed to resolve inspection issues and the agency recommended the company's CLIA certification be revoked for that California lab.

CMS recommended that Theranos lose its CLIA certification unless the lab provides evidence that the recommended sanctions shouldn't be imposed. That was based on an inspection that took place late last year where the agency determined Theranos' Newark, Calif., laboratory had condition level deficiencies and posed an immediate danger to patients in the area of hematology.

Theranos had provided corrective action in response to the initial letter regarding the inspection, but CMS concluded that the lab's corrective actions were not credible, noting instances where Theranos plans were non-specific. Theranos can appeal the CLIA certificate revocation if it is imposed. CMS also recommended limitations on the lab's performance of hematology assays that would take place almost immediately. Theranos faces a $10,000 daily fine for non-compliance. Additionally, CMS also requested a list of all providers who have used the lab since January to notify them of the ongoing issues at the facility.

CMS' 147-page inspection report charted a number of omissions and failures in the operation of the laboratory (Theranos' facility in Arizona was not included in this report or the sanction recommendations). Among them:

- Preanalytic systems and relevant documentation when specimens were referred to other labs for testing failed.
- Corrective actions for chemistry quality control were not in place.
- The proper calibration of equipment failed.
- The laboratory director failed to sign off on mandated procedures or changes to procedures.
- Appropriate temperature ranges were not maintained for freezers.
- Appropriate guidelines to maintain the integrity of quality control materials were not followed.
- The laboratory failed to notify a patient or patients of errors in their test results in a timely fashion.

There were some redactions to the report, including the annual test volume of the laboratory.

Meanwhile, as our sister publication *Laboratory Industry Report* reported, a group of researchers from one of the most prestigious teaching hospitals in the nation questioned the validity of Theranos' testing platform in a study published in the *Journal of Clinical Investigation*. Researchers from the Icahn School of Medicine at Mt. Sinai Hospital New York had 60 patients undergo common testing via Theranos' retail sites in Arizona last year, and compared the results against more traditional venipuncture testing at LabCorp and Quest Diagnostics. The study included more than 18,000 data points and flagged tests outside its normal range of results 1.6 times more often than Quest and LabCorp. Of the 22 lab measurements evaluated, 15 (68 percent) showed significant in-

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>
> **—Janet B. Kreizman, CEO, AACC**

terservice variability. And 2.2 percent of Theranos' data results were missing, compared to 0.2 percent for LabCorp and no missing results for Quest. Theranos criticized the test results and the integrity of the study and its researchers, who it claimed didn't disclose participation in a company Theranos labeled a competitor.

Finally, *Bloomberg* and *The Wall Street Journal* reported that in a memo to Theranos partners the company revealed it is the subject of investigation by the U.S. Securities and Exchange Commission and the U.S. Attorney's Office. Theranos Chief Executive Officer Elizabeth Holmes also appeared on NBC's *Today* show in an interview with Maria Shriver and indicated she was "devastated" that her company didn't catch problems earlier and she vowed to fix the problems and continue her company's mission.

Holmes will soon have another public forum in which to talk about her company's mission. She is slated to present at the American Association for Clinical Chemistry's 68th annual scientific meeting in Philadelphia on Aug. 1. "There is no better place to present Theranos' technology than at the AACC Annual Scientific Meeting, where leaders in laboratory medicine can evaluate Ms. Holmes' data and research," said AACC CEO Janet B. Kreizman, in a statement.

Takeaway: As the number of federal agencies scrutinizing Theranos operations increases, CEO Elizabeth Holmes vows to continue the company's mission.

G2 Compliance Corner

Take Steps Now to Establish Quality Systems for LDTs

Strengthened oversight of laboratory developed tests is drawing nearer as the U.S. Food and Drug Administration has predicted a 2016 release of a finalized framework for that oversight. While opposition is strong and legislation could impose an alternative to the FDA's proposal, it is still wise for laboratories to begin taking steps to prepare for heightened scrutiny and increased compliance requirements for LDTs. Impending regulation of LDTs was one of the challenges discussed at G2 Intelligence's Lab Revolution held last month at the Sheraton Wild Horse Pass Resort and Spa in Chandler, Ariz. (April 6-8).

At that conference, a panel highlighted the FDA's proposal and its impact on laboratories. Michael Murphy, president of Conatus Consulting, and Richard S. Robinson MT (ASCP) from the American Red Cross Biomedical Headquarters Regulatory Affairs reviewed the current status of the FDA proposal and provided some practical advice to help labs prepare for anticipated new oversight. Murphy emphasized the importance of developing quality systems and noted that in the 20 cases the FDA mentioned in their recent report concerning problematic LDTs, errors were due to "extremely deficient" quality control. In the short term, he recommended labs focus on quality systems, design controls and document controls. To begin establishing a quality system he recommended laboratories take four steps: 1) conduct a gap analysis, 2) get management buy in, 3) develop SOPs, and 4) train employees. Rather than taking a wait and see approach and having to play "catch up" to comply with increased regulation, laboratories would be wise to begin structuring quality systems now.

Editor's Note: For more guidance on how to prepare for LDT regulation, G2 Intelligence will be presenting a 90-minute webinar, *FDA Regulation of Laboratory-Developed Tests: What to Expect, How to Prepare*, on May 24, 2016, at 2 p.m. EST, with Mahnu Davar and Jen Madsen, MPH of Arnold & Porter's Life Sciences and Healthcare Regulatory Practice. For more information, visit www.g2intelligence.com/web/

News at a Glance

PAMA Final Rule under OMB Review. The Centers for Medicare & Medicaid Services' final rule implementing the Protecting Access to Medicare Act of 2014 (PAMA) is now under review by the White House Office of Management and Budget (OMB). The highly anticipated rule is expected to require Medicare payment for clinical laboratory tests to be based on private payor rates beginning Jan. 1, 2017. OMB began its review of the final rule on April 21. Regulatory clearance—and subsequent publication in the *Federal Register*—is widely expected to be imminent. A proposed version of the rule, published in the *Federal Register* on Oct. 1, 2015, outlined CMS' plan for determining commercial rates. It called for collecting price data from laboratories that receive at least half of their Medicare revenues from lab-test reimbursement. Industry concerns include potential that exclusion of hospital-based labs would yield CLFS rates not representative of overall market rates and the schedule for implementation of CMS's new reporting and payment methodology. "We believe the critical alterations to the CLFS must be accomplished in a deliberate and measured manner, so that laboratories have sufficient time, once the final rule and sub-regulatory guidance are issued, to comply," wrote House Ways and Means Health Subcommittee Chairman Pat Tiberi and 26 other committee members in a March 31 letter to Acting CMS Administrator Andy Slavitt.

Sequenom to Petition U.S. Supreme Court to Regain MateriT21 Test Patent. Molecular testing firm Sequenom has decided to petition the United States Supreme Court in an attempt to regain a patent for a genetic test it lost three years ago. The petition is centered around what has been referred to as the "540 patent," in reference to the last three numbers of a patent Sequenom held until 2013 that it applied to its MateriT21 test. That assay is used to analyze cell-free fetal DNA (cffDNA) in a mother's blood to diagnose genetic conditions. Sequenom had claimed that Ariosa Diagnostics's Harmony Prenatal Test and Natera's Non-Invasive Paternity Test (licensed to DNA Diagnostics Center, Inc.) infringed the '540 patent. Last year in June, the Federal Circuit Court of Appeals affirmed a ruling that Sequenom's '540 patent relating to cffDNA failed to assert claims that were patent eligible. In December, the appellate court denied Sequenom's request for a rehearing. However, one dissenting judge, Pauline Newman, an appointee of President Ronald Reagan, observed that "the new diagnostic method here is novel and unforeseen, and is of profound public benefit" and claimed that "[p]recedent does not require that all discoveries of natural phenomena or their application in new ways or for new uses are ineligible for patenting; the Court has cautioned against such generalizations." Sequenom argues "overly-expansive patent eligibility criteria have not only negatively impacted Sequenom's patent, but have put into jeopardy the patentability of existing and future diagnostic method patent claims."

Labs Want Congress to Intervene on LDT Regulation. A pending FDA/agriculture appropriations bill in Congress includes a provision that would suspend final regulations for the FDA's oversight of laboratory-developed tests (LDTs). Instead, the agency would be directed to work with federal lawmakers to create a pathway for regulating such assays. The bill was approved by the House Appropriations Committee on a voice vote and likely has significant supporters in both the House of Representatives and the Senate, according to Alan Mertz, president of the American Clinical Laboratory Association (ACLA). "It should send a message to the FDA that Congress is interested in a legislative solution," Mertz said, acknowledging that while Congress has weighed in on reimbursement issues for the sector on multiple occasions, it has not really involved itself on the regulatory end for decades.

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