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INSIDE THIS ISSUE

PAMA: The New LAB Act Buys Labs One Year of Price Reporting Relief

The lab industry has been making slow but steady progress in its quest for PAMA relief. After winning a federal court appeal preserving its right to challenge CMS's PAMA pricing systems, the industry achieved one of its key legislative priorities for 2019, passage of the *Laboratory Access for Beneficiaries Act* (LAB Act), which delays the next round of PAMA reporting for one year. Here's a rundown of the LAB Act and where things stand with regard to the larger PAMA situation.

The LAB Act

The *Protecting Access to Medicare Act* (PAMA) requires CMS to base Medicare Part B lab test reimbursement rates on the actual market prices labs charge private payors. To carry out this mandate, CMS requires participating labs to report pricing information and then uses the data to set rates for particular tests under the Clinical Laboratory Fee Schedule (CLFS). While price reporting is all well

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Enforcement Trends: The Top 5 Lab False Claims Act Settlements of 2019

Labs were on the paying end of at least eight million-dollar *False Claims Act* (FCA) settlements or judgments in the 2019 fiscal year. Here's a review of the top 5 reported FCA recoveries against a lab or lab services company. (Go to the G2 website if you want more details on any of these cases.)

1. Inform Diagnostics Settles EHR Consulting Services Kickback Claims for $63.5 Million

An Anti-Kickback Statute safe harbor and Stark Law exception allows non-physician providers to pay up to 85% of physicians' costs to help them transition from paper records to EHR systems.

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The New LAB Act Buys Labs One Year of Price Reporting Relief, *from page 1*

and good, the problem with the CMS scheme is that it excludes hospital labs, a group that not only represents a significant part of the market but also commands higher prices due to its relatively greater leverage vis-à-vis private payors. As a result, current reporting results in lab prices artificially low in direct opposition to the PAMA mandate of implementing truly market-based pricing.

At the start of 2019, CMS gave some ground by extending PAMA reporting to a segment of hospital labs. But the change was abrupt and many hospital labs weren't prepared to meet their reporting obligations on time.

Labs were supposed to report the next round of pricing data between Jan. 1 and March 31, 2020. The plan was for CMS to use that data to set CLFS lab test rates for the next three years, beginning on Jan. 1, 2021. The LAB Act, which was passed as part of an end-of-year spending package, delays that process by a year. That's a big deal because it gives hospital labs more time to collect payment data and thereby increase their participation in the process.

The LAB Act also paves the way for additional PAMA reforms by commissioning a study on how to improve data collection and rate setting to better reflect Congress' original intent of a market-based fee schedule for clinical lab services. "Fortunately, Congress' decisive action puts us on the path to enact meaningful PAMA reforms that will protect seniors' access to essential lab services, as the law originally intended," noted American Clinical Laboratories Association (ACLA) President **Julie Khani** in a statement.

Impact of LAB Act

Giving hospital labs more time to report pricing data won't prove meaningful if they're not willing to go along with the idea. The American Hospital Association (AHA) opposed CMS' move to require hospital labs to collect and report private payor data under PAMA, arguing that the burden of reporting this data outweighs whatever boost in pricing reporting might provide. The refusal of many hospital labs to participate could limit the LAB Act's effectiveness. However, the delays enacted by the law would give the industry time to pursue other efforts to blunt PAMA's impact, most notably ACLA's ongoing lawsuit challenging the rate-setting process.

The LAB Act also offers nothing in the way of immediate price relief. According to Wall Street analyst **William Quirk**, while the data collection would originally have provided a "small positive update" in 2021 lab reimbursements, the delay will impact 2022 pricing, instead, as reimbursements in 2021 under PAMA will be based on the original PAMA schedule from data collected during the 2017 period and not the 2020 reporting period. He added the delay is "incrementally negative" for the LabCorp and Quest.

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Enforcement Trends: False Claims Act Recoveries Increase as Labs Remain in Firing Line

The dollars paid by healthcare providers in federal False Claims Act settlements and judgments increased for the second year in row in 2019. After a surprising decline in 2017, total recoveries rebounded in 2018 from $2.184 billion to $2.513 billion. This year, the increase was more modest at $2.6 billion. Even so, 2019 marked the 10th straight year that FCA recoveries topped $2 billion. And, as usual, the health care industry was the primary source of recoveries, accounting for more than $5 of every $6 collected in 2019.

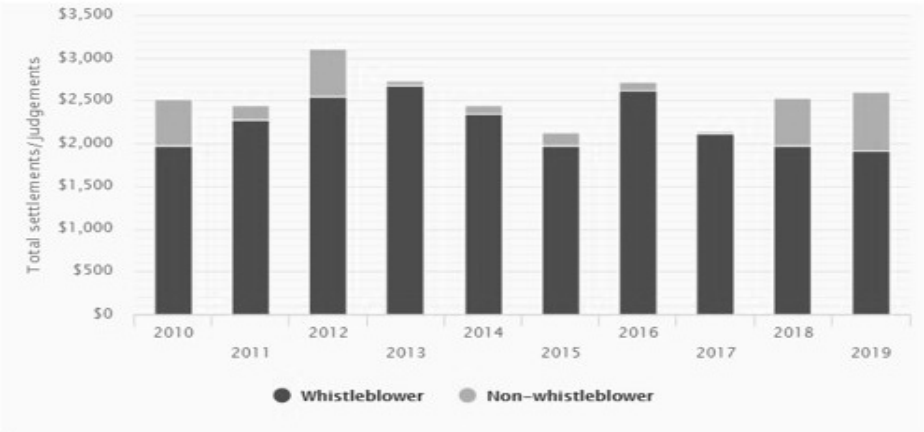
2019 By the Numbers

Here are the key numbers from the year in 2019 FCA recoveries, as reported by the DOJ on Jan. 9:

- **$3 billion:** Total FCA recoveries in FY 2019;
- $2.6 billion: Total recoveries against health care providers in FY 2019 (not including state Medicaid);
- **$47 billion:** Total FCA recoveries against health care providers between 2010-2019;
- **$3.7 billion:** Average annual FCA recoveries for three-year period 2016-2018;
- **$22.7 billion:** Total FCA recoveries from healthcare providers between 2009-2018;
- **$1.96 billion:** Average annual FCA recoveries from health care providers between 2010-2019;
- **633:** Total *qui tam* (whistleblower) lawsuits filed in FY 2019, an average of 12 cases per week;
- **$2.1 billion:** Total recoveries in *qui tam* lawsuits in FY 2019.

Healthcare Fraud Recoveries

The amount of settlements and judgements obtained by the U.S. Justice Department from whistleblower and non-whistleblower False Claims Act cases, 2010 to 2019



Notes
$ in millions
Source: U.S. Justice Department

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False Claims Act Recoveries Increase as Labs Remain in Firing Line, *from page 3*

Top 3 FCA Healthcare Recoveries

The biggest FCA recovery against a lab in 2019 was the $63.5 million settlement paid by Inform Diagnostics (the pathology lab company formerly known as Miraca Life Sciences Inc.) for allegedly paying kickbacks to referring physicians in the form of subsidies for electronic health records (EHR) systems and free or discounted technology consulting services. (See page 1 for a summary of the top 5 FCA settlements involving labs.) But drug companies were the real cash cow for federal FCA enforcement, accounting for the year's three largest recoveries, including:

1. **Reckitt Benckiser Group plc** paid $500 million as part of a larger $1.4 billion settlement resolving FCA and other civil and criminal claims for falsely marketing the opioid addiction treatment drug Suboxone;
2. **Insys Therapeutics** paid $195 million to settle claims of offering sham speaker events, lavish meals and entertainment and even jobs to induce physicians and nurse practitioners to prescribe Subsys for their patients;
3. **Avanir Pharmaceuticals** paid $95+ million to resolve allegations that it paid kickbacks and engaged in false and misleading marketing to bribe providers in long term care facilities to prescribe the drug Neudexta for dementia patients, which is not an FDA approved use of the drug.

In addition, the DOJ report notes that seven drug manufacturers—Actelion Pharmaceuticals US Inc.; Amgen Inc.; Astellas Pharma US Inc.; Alexion Pharmaceuticals, Inc.; Jazz Pharmacueticals Inc.; Lundbeck LLC; and US Worldmeds LLC—paid a combined total of over $624 million to settle claims of illegally paying patient copays for their own drugs via purportedly independent foundations that the companies in fact treated as mere conduits.

FCA Recoveries against Healthcare Providers Since 2010

(in billions of dollars)

Year	*Qui Tam* Recovery against Healthcare Providers	Total Recovery against Healthcare Providers
2010	$1.9	$2.5
2011	$2.2	$2.4
2012	$2.5	$3.1
2013	$2.6	$2.7
2014	$2.3	$2.4
2015	$1.9	$2.1
2016	$2.6	$2.7
2017	$2.1	$2.1

Year	*Qui Tam* Recovery against Healthcare Providers	Total Recovery against Healthcare Providers
2018	$1.9	$2.5
2019	$1.9	$2.6
Total	$21.9	$25.1

Source: U.S. Department of Justice

Takeaway

The DOJ's reporting of FY 2019 FCA fraud recoveries show that large scale enforcement efforts are continuing—and that while drug companies are paying out the largest share of dollars, lab testing remains a major target for enforcement agencies.

ACA: Still Here Today but for How Much Longer?

Is Obamacare really dead? Only partially dead? Or is it totally alive? It's all pretty confusing. But the short answer is that Obamacare lives and will continue to do so unless and until the U.S. Supreme Court strikes it down. The good or bad news, depending on how you feel about the issue, is that we're drawing closer to the moment when the Supreme Court will have the opportunity to make that determination. On the other hand, they may just uphold the law, or at least part of it. And all the while, there remains the possibility, fairly unlikely, that Congress will get together and create a new law to replace Obamacare. If you want more details, keep reading.

The Recent 5th Circuit Ruling

On Dec. 18, the U.S. Court of Appeals for the 5th Circuit issued a ruling striking down part of Obamacare, aka, the *Affordable Care Act* (ACA), as unconstitutional. Specifically, the court found that the ACA individual mandate, i.e., the requirement that Americans carry health insurance or pay a tax penalty, is unconstitutional. But the Republicans bringing the case, *Texas v. United States*, didn't get what they were really hoping for—and even expecting—a ruling finding the entire law unconstitutional. In other words, they recognized that the Fifth Circuit opens the door to saving the body of the ACA by removing the individual mandate tumor.

This position clashes directly with the lower federal court ruling of December 2018 holding that the ACA is a package deal of which the individual mandate is an essential part of that couldn't be severed from the rest of the law. So, if the mandate was unconstitutional, the whole law must be unconstitutional as well. But the 5th Circuit wasn't prepared to take it that far. Explain your reasoning and analysis more clearly, it instructed the lower court, and we'll decide if you're right.

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ACA: Still Here Today but for How Much Longer?, *from page 5*

Practical Impact

The punchline of the 5th Circuit ruling is that it decides nothing and serves only to prolong the case for another year by returning it to the lower court. The 5th Circuit's ruling that the ACA mandate is unconstitutional is a moot point because Congress has already effectively eliminated the tax penalty for penalty for people who don't have health insurance. The ruling doesn't address what's really at stake, namely the fate of the other elements of the ACA law at risk of being struck down, including:

- Insurance subsidies for people who acquire health plans through ACA marketplaces;
- The expansion of Medicaid in three dozen states;
- The requirement that insurers cover people with pre-existing conditions;
- The ability of young adults to stay on their parents' insurance policies until they turn 26; and
- No-charge preventive care for older Americans on Medicare.

If the entire ACA is declared unconstitutional, an estimated 17 million Americans would lose health care coverage, and more than 50 million people with pre-existing medical conditionals could be denied health insurance.

A complete repeal would also play havoc with insurers by abolishing the ACA marketplaces. This would be devastating to managed care organizations like Anthem, Cigna, Centene that have invested so much to establish themselves in the ACA marketplaces.

Repeal would also have significant ramifications to the extent the ACA is also woven more subtly into many other aspects of the health-care system, from payment formulas for hospitals and doctors to experiments intended to nudge health-care from a system that pays for the quantity of medical services to one based on the value of care patients receive. Additionally, if ACA is declared unconstitutional, it could undermine the Trump administration's proposals to lower drug prices.

The Latest Twist

Technically, the *US v. Texas* case isn't ripe for Supreme Court review because it still has to go back down to the lower court and thence through the 5th Circuit. But on Jan. 3, a coalition of Democratic governors and attorneys general from 20 states argued that the matter can't wait and took the unusual step of calling on the Supreme Court to step in and decide the case before the Court's current term ends in June. "Uncertainty threatens adverse consequences for patients, providers and insurers nationwide," according to their petition.

The ACA 20

The states that filed the petition asking the Supreme Court to rule on the US v. Texas case by June include California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Iowa, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New York, North Carolina, Oregon, Rhode Island, Vermont, Virginia, Washington and the District of Columbia, as well as the Governor of Kentucky.

What Happens Next?

For the Supreme Court to take the case on an expedited basis, five of the nine justices will have to agree to hear it. Scheduling constraints dictate that the Court make and publicize its decision on the petition within a few weeks. University of Michigan law professor **Nicholas Bagley**, writing in the *New England Journal of Medicine*, suggests that the four liberal justices on the Court may opt to accept the case and then count on persuading Chief Justice John Roberts to do the same and ultimately uphold the law, the same formula that led to the upholding of the individual mandate in *NFIB v. Sebelius* decided by the Court six years ago. Justice Roberts has twice turned back more substantial challenges to the law and is unlikely to embrace a lawsuit as weak as this one, the professor argues.

FDA Watch: FDA Targets Sale of IVD Reagents without Premarket Approval

Distribution of diagnostics and devices without premarket approval has featured prominently on the FDA's enforcement priority list this year. The agency has issued seven warning letters related to premarket approval in 2019 after issuing just one such warning letter in all of 2018.

Carolina Liquid Chemistries was on the receiving end of the most recently announced warning letter, which contends that the Greensboro-based firm sold Class I and II *in vitro* diagnostic (IVD) reagents without obtaining the necessary premarket approval. More specifically, Carolina Liquid failed to produce evidence showing that distributions of Tapentadol, Zolpidem, Spice and Fentanyl reagents branded only for forensic or research and development were restricted to appropriate research centers, law enforcement agencies or court mandated testing centers. The agency suspects that the reagents might have also been sold to pain management centers and a clinical testing laboratory for unapproved clinical testing applications. The FDA raised concerns about the sales history of Carolina Liquid reagents branded as for forensic and research use while inspecting the company's facilities last year.

PAMA Report: ACLA Tries for Decisive Blow in Federal Court Case

Now that its lawsuit challenging the PAMA pricing scheme is back in the lower federal court, the American Clinical Laboratory Association (ACLA) went back on the offensive by moving for summary judgment on Oct. 15. ACLA contends that CMS' scheme for implementing PAMA's market-based prices for lab tests is "unreasonable" and contrary to the intent and terms of the statute. The agency's decision to exclude hospital labs from data collection resulted in artificially low prices that don't reflect true market rates, according to the ACLA. The new ACLA motion invites the court to rule in its favor without a trial.

The Larger PAMA Picture

Even if ACLA prevails on the summary judgment motion, CMS would likely appeal to the federal circuit court, just the way ACLA did last year when the roles were reversed and CMS won on summary judgment. Were it to ever happen, a decisive litigation outcome would require years, and maybe even a ruling by the U.S. Supreme Court. (For more on the PAMA court challenge, see *Lab Compliance Advisor (LCA)*, Sept. 10, 2019.)

The real action as far as PAMA goes, is at the negotiating table. Negotiations between CMS and the lab industry have already yielded relief in the form of broadened "covered laboratory" criteria to include some hospital labs in PAMA pricing contained in the 2019 Clinical Laboratory Fee Schedule (CLFS). (For more on the 2019 PAMA changes, see, *Lab Compliance Advisor (LCA)*, Jan. 21, 2019). The ACLA court challenge increases the lab industry's bargaining leverage and exerts pressure on CMS to make further concessions.

A similar dynamic is at work on the legislative front where a new bill called the LAB Act would delay PAMA reporting pending a thorough review of the CMS market-based pricing implementation scheme. Unlike the court case, the LAB Act could provide real, decisive and immediate relief. (For more of the LAB Act, see *National Intelligence Report (NIR)*, July 16, 2019). But passing legislation is never easy, particularly during an election year and particularly in the current political environment.

Takeaway

At long last, the lab industry seems to be making significant progress in its quest to get CMS to back away from its misguided and harmful PAMA pricing rules. The industry's Plan A remains getting CMS to make regulatory concessions, the way it did with the new 2019 CLFS hospital lab reporting rules. Plan B is to reverse the CMS system via the LAB Act or other legislation. The lawsuit is only Plan C. And while a decisive court victory is the longest of long shots, pursuing the case keeps the heat on CMS and enhances the effectiveness of Plan A.

In Brief: OIG Opens Second Avenue for Anti-Kickback Statute Revisions

Even as we wait for the second draft of the proposed new value-based kickback relief rules—see *National Intelligence Report (NIR)*, Nov. 15, 2019—the OIG issued its annual call for recommendations for new or revised Anti-Kickback Statute safe harbors. From now through March 2, 2020, the agency will entertain suggestions and evaluate them on the basis of whether they would increase or decrease:

- Access to healthcare services;
- Quality of healthcare services;
- Patient freedom of choice among healthcare providers;
- Competition among healthcare providers;
- Costs to federal healthcare programs
- Potential overutilization of healthcare services; and
- The ability of healthcare facilities to provide services in medically underserved areas or to medically underserved populations.

In the News: Quest Shells Out $195K to Settle Massive HIV Data Breach Class Action

Government fines, public embarrassment, loss of provider and patient trust. As if these consequences weren't scary enough, massive PHI breaches can expose your lab to a new kind of risk: class action lawsuits by those whose personal information was compromised. Exhibit A is the recent case against Quest Diagnostics.

The case began in November 2016 when a massive cyberattack compromised the PHI of nearly 12 million people. Among the victims, the hackers were able to gain access to the SSNs, HIV test results and other personal information of Quest patients via the MyQuest by Care360 internet app. Rather than chase after Quest individually, a group of 34,000 victims banded together to bring a massive class action accusing Quest of negligently failing to safeguard their PHI and provide them timely notification of the breach, among other things.

Quest denies the allegations. And who knows what would have happened had the case proceeded to trial. But as is often the case when confronting the risk of not only liability but also liability multiplied by the number of class members, it decided to settle the case. The cost: $195,000, including $250 to each individual who can demonstrate they suffered monetary loss as a direct result of the breach. Individuals who can show their HIV test results were accessed will be entitled to an additional $75.

By the Numbers: Improper Medicare Payments Hit 10-Year Low

As 2019 came to an end, CMS announced that the rate of improper Medicare payments during the year continued to decline, hitting its lowest point since 2010. Here are some of the key numbers:

- **$28.91 billion:** Approximate amount of improper payments made by CMS in fiscal year 2019
- **7.25:** Percentage of fee-for-service Medicare claims that were improperly paid in FY 2019
- **$31.6 billion:** Approximate amount of improper payments made by CMS in FY 2018
- **8.12:** Percentage of fee-for-service Medicare claims that were improperly paid in FY 2018
- **3:** FY 2019 is the third consecutive year that the improper payment rates was below 10%

Takeaway

Steadily declining rates of improper payments, which include overpayments, underpayments, fraudulent claims, payments distributed to the wrong recipient or for the wrong amount, payments with insufficient documentation and those when the recipient uses the funds improperly, is, of course, welcome news. But don't expect regulators and enforcers to back off anytime soon. On the contrary, CMS attributed the decline in improper payment rates to its "aggressive program integrity measures," a strategy that's sure to continue for the foreseeable future.

The Top 5 Lab False Claims Act Settlements of 2019, *from page 1*

But Inform Diagnostics (then known as Miraca Life Sciences Inc.) allegedly stretched the rules beyond the breaking point by offering physicians discounts on EHR consulting services in exchange for lab referrals. It even based individual discount amounts on the anticipated return on investment the particular physician's referrals would generate and offered the deal only to physicians it targeted as high-volume referral sources. Three different whistleblowers filed *qui tam* lawsuits and when the Department of Justice (DOJ) decided to intervene, Inform saw the writing on the wall and has agreed to settle the claims for $63.5 million.

2. Jewish Hospital & St. Mary's Healthcare Settles *Qui Tam* Claims for $10.1 Million

Ending a case that began as a *qui tam* whistleblower lawsuit, Jewish Hospital & St. Mary's Healthcare Inc., d/b/a Pharmacy Plus and Pharmacy Plus Specialty, agreed to pay $10.1 million to settle claims of falsely billing for prescription drugs that weren't medically necessary. In addition

to serious documentation issues—orders unsigned by a physician and absence of records showing that medications were actually delivered, the hospital allegedly paid kickbacks to patients in the form of free blood glucose testing supplies and waiver of co-payments and deductibles for insulin. The pharmacist who brought the original *qui tam* claims received $1.85 million of the settlement.

3. Myriad Genetics Settles Hereditary Cancer Test False Billing Claims for $9.1 Million

This whistleblower suit alleged false billing for the Myriad myRisk Hereditary Cancer, a 25-gene panel that blends genetic test status and personal/family cancer history to identify clinically significant mutations affecting inherited risks for eight hereditary cancers. The billing problems may have stemmed from Myriad's use of CPT Code 81211, which describes full sequencing analysis of BRCA genes together with CPT Code 81213, describing duplication and delection analysis of the genes. After a 17-month investigation, the DOJ declined to intervene. And Myriad firmly insisted that it was innocent. But faced with the uncertainties of trial and risk of treble damages, the company decided that discretion was the better part of valor and settled the case for $9.1 million.

4. Nevada Heart & Vascular Center Settles Genetic Test Fraud Allegations for $2.5 Million

The feds accused Nevada Heart & Vascular Center (NHVC) of taking kickbacks from a pair of now defunct genetic testing companies, Natural Molecular Testing Corp. and Iverson Genetic Diagnostics, Inc., in exchange for referrals of Medicare patients over a roughly two-year period starting in September 2012. Rather than risk trial, NHVC shelled out $2.5 million to settle the case. The $2.5 million recovered from NHVC is chump change compared to the $90 million in fraudulent payments ($71 million to Natural Molecular and $19 million to Iverson) allegedly made to the labs that declared bankruptcy before CMS could get any of that money back.

5. GenomeDx Biosciences Settles Genetic Testing False Billing Claims for $1.99 Million

In a case that began as a whistleblower suit filed by two ex-employees, GenomeDx Biosciences agreed to shell out $1.99 million to settle charges of improperly billing Medicare for its Decipher Biopsy which predicts the probability of prostate cancer metastasizing after surgery and classifies the tumor's aggressiveness. The government claimed that over a nearly two-year period, beginning in September 2015, the San Diego-based genetic testing company made claims for Decipher tests performed on patients who didn't have risk factors making the tests medically necessary. The whistleblowers got $350K of the settlement.

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The Top 5 Lab False Claims Act Settlements of 2019, *from page 11*

The 3 Takeaways

1. Whistleblowers: The first thing worth noting is that with the exception of NHVC, all of these cases began as whistleblower lawsuits. This is no deviation. Thus, of the total $2.6 billion the DOJ recovered in FCA actions against healthcare providers in 2019, $2.1 billion started as *qui tam* suits. (See the related article on page 3.)

2. Settlements: Although recoveries include judgments and settlements, the vast majority of FCA cases settle without a trial. Combining this with the previous point about whistleblowers, the key to defending against *qui tam* lawsuits is to knock them out early. As in much civil litigation, the crucial point is the lab/defendant's motion for summary judgment, i.e., request that the court dismiss the case without a trial. If the motion is denied, the risk calculus for the lab increases exponentially. It gets ratcheted up even higher should the DOJ decide to intervene. At this point, the costs of a defense and risks of liability tend to outweigh the benefits of proceeding, no matter how strong the lab feels its case is.

3. Genetic Tests: Three of the top 5 FCA lab settlements involved false billing of genetic testing. That is no coincidence. As genetic testing comes into wider use, the scrutiny of enforcers has intensified. 2019 was a breakthrough year with Operation Double Helix, the multi-state federal initiative targeting a $2.1+ billion nationwide genetic testing fraud scam. See *National Intelligence Report (NIR), Oct. 29, 2019*, to find out more about Operation Double Helix and its significance on lab enforcement. You can be sure that whistleblower cases against genetic testing labs will continue to increase in the years ahead.

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