G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

April 2018

INSIDE THIS ISSUE

www.G2Intelligence.com

Upcoming Events

Lab Institute 2018

Surviving Disruption: Rethinking Business Models, Technologies, and Competitive Strategies in a Changing Lab Market

Oct. 24-26, Washington, DC
www.labinstitute.com

Enforcement Trends: Why Fending Off Whistleblowers Might Have Just Gotten Easier

Because government enforcers cannot be everywhere at once, the *qui tam* whistleblower lawsuit was invented. The result has been a proliferation of fraud cases against not just labs and health care providers but all firms that do business with the federal government. But what often goes overlooked is the burden that all of these cases, some of which lack merit, put on the enforcement infrastructure. And now a newly leaked internal Justice Department memo suggests that the government is determined to apply the brakes and discourage whistleblowers from bringing *qui tam* lawsuits—or at least those of dubious merit. Here is a look at the policy and why it may be good news for your lab and its compliance officers and attorneys.

Continued on page 2

Brief Your CEO: The New CMS Appeals Process & How to Use It to Get Medicare to Pay

While Part B lab reimbursements may be going down, the good news is that it just became easier to challenge Medicare payment denials. On Feb. 5, 2018, CMS launched a new Low Volume Appeals settlement process that your lab may be in the position to take advantage of. So you may want to explain the process and how it works in your next compliance briefing for the C-Suite. Here's how:

Prologue: Make Sure Your Lab Is Eligible

Of course, there is no sense doing a briefing on the LVA appeals settlement process unless and until you make sure your lab is in the position to participate in it. The process is open to Medicare Part A and Part B providers, including labs, as well as physicians and suppliers (referred to collectively as "appellants") with fewer than 500 combined pending appeals with the Office of Medicare and Appeals and Medicare Appeals Council (Council) at the Departmental Appeals Board as of Nov. 3, 2017. Your lab is **not** eligible if it is currently involved in *False Claims Act* (FCA) litigation or subject of a pending criminal, civil or administrative investigation for FCA or other program integrity concerns. Other ineligible appellants include:

Continued on page 9

Enforcement Trends: Why Fending Off Whistleblowers Might Have Just Gotten Easier, *from page 1*

Qui Tam, 101

The so called *qui tam* provisions of the *False Claims Act* (FCA) allow individual whistleblowers, known as "relators," to act as private attorneys general and sue companies for ripping off the government. In addition to being moral, whistleblowing can also be highly profitable. If the suit is ultimately successful, the government can collect triple damages and the relator can walk away with up to 35% of the recovery.

But there are also big risks. FCA cases must be filed under seal to give the DOJ time to investigate and decide whether it wants to intervene:

- If the government joins, pressure mounts on the defendant to settle the case; but
- If the government declines, the relator can still go forward with the case but with far less leverage and legal firepower.

There is also one other possible outcome, at least on paper. The FCA (Section 3170(c)(2)(A)) actually gives the government the right to seek dismissal over the relator's objection if it thinks its interests are not served by the suit. But while it is on the books, the DOJ almost never uses its Section 3170(c)(2)(A) dismissal powers.

The Granston Memo

An internal memo issued by DOJ Civil Fraud Section Director Michael Granston on Jan. 10 aims to change that. The so called Granston Memo instructs U.S. Attorneys to use Section 3170(c)(2)(A) more aggressively. The right to seek dismissal is an important "tool" enabling the DOJ to exercise its "gatekeeper role" in preserving enforcement resources, protecting government interests and preventing weak cases from resulting in adverse judgments that weaken the government's enforcement powers.

The Memo sets out seven factors that U.S. Attorneys should consider in deciding whether to seek dismissal of a whistleblower suit under Section 3170(c)(2)(A):

1. Meritless Claims, i.e., where a *qui tam* complaint appears to be lacking in merit because the relator's legal theory is "inherently defective," or because his/her "factual allegations are frivolous."

2. Parasitic or Opportunistic Claims, i.e., *qui tam* actions that duplicate pre-existing government investigations and add no useful information to the investigation and bestow the relator with an unwarranted windfall in taxpayer dollars for providing merely duplicative information.

3. Threats to Policies or Programs, i.e., *qui tam* actions that threaten to interfere with a government agency's policies or programs.

4. Actions Interfering with Other FCA Cases, e.g., a separate *qui tam* case in which the government has already chosen to intervene.

5. Cases Threatening Harm to National Security Harm, e.g., *qui tam* actions that may compromise classified information, involve intelligence agency operations or military contracts.

G2CA

Glenn S. Demby, Editor

Lori Solomon, Contributing Editor

Catherine Jones, Contributing Editor and Social Media Manager

Barbara Manning Grimm, Managing Editor

David van der Gulik, Designer

Randy Cochran, Corporate Licensing Manager

Myra Langsam, Business Development

Michael Sherman, Director of Marketing

Jim Pearmain, General Manager

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

G2 Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

6. Cases Where Costs Will Exceed Gain, the calculation of which should include the "opportunity cost" of utilizing resources on other matters of higher priority with a surer probability of recovery.

7. Claims that May Frustrate an Investigation, i.e., whether there are issues, such as procedural errors, with the relator's action that frustrate the government's effort to conduct a proper investigation.

Takeaway: It remains to be seen whether prosecutors actually follow the Granston Memo guidance. But if they do, it might lead to a reduction of qui tam *suits by discouraging whistleblowers and their attorneys from asserting questionable claims. While such an impact would benefit all industries covered by the FCA, health care would reap the greatest benefit considering the disproportionate number of* qui tam *claims targeting that sector.*

If it takes, the new Granston Memo policy may also strengthen the hand of attorneys defending your lab in a qui tam *suit under seal by offering a new strategic option: Leveraging one or more of the seven Granston Memo factors to urge the US Attorney to seek a Section 3170(c)(2)(A) dismissal of the suit.*

CMS to OIG: Get Back the $66.3 Million You Improperly Paid to Labs for Urine Validity Tests

As if times were not already tense enough for labs that bill Medicare for urine drug tests, the OIG ratcheted up the pressure another notch on Feb. 20 by issuing a new report chiding CMS for making $66.3 million worth of improper payments for such tests. More precisely, the assays called out by the OIG are specimen validity tests billed in combination with urine drug tests. Here is an overview of the report and what it may portend for providers of Part B lab tests.

Urine Drug & Specimen Validity Testing

Under Medicare rules, urine drug testing is deemed medically necessary to detect and quantify the presence of drugs in a patient's body. Specimen validity testing, which analyzes the urine specimen to ensure that it has not been adulterated or tampered with, is not deemed medically necessary if its sole purpose is to validate the specimen since the test results are not being used to manage the beneficiary's treatment.

Exception: Specimen validity testing is medically necessary in limited cases when it is used in combination with a urine drug test done on the same day for purposes of diagnosing certain conditions such as kidney stones or urinary tract infection. However, the latter cases should be relatively rare, according to CMS officials cited in the report.

OIG Findings

With that in mind, the OIG audited $67+ million in Medicare Part B payments for specimen validity tests billed in combination with urine drug tests,

Medicare contractors should recover the $66.3 million it improperly paid out for specimen validity testing.

i.e., on the same dates of service, from 2014 through 2016. The findings: $66.3 million of the payments were improper. Those payments were received by 4,480 clinical labs and physician offices. The report cites two reasons for the improper payments:

- The providers' failure to follow existing Medicare guidance; and
- The inadequacy of CMS system edits designed to prevent payment for specimen validity tests billed in combination with urine drug tests.

In fact, CMS did implement revised edits on April 1, 2016. But while the revised edits helped, $1.8 million worth of improper payments still got past the goalie during the first nine months they were in place. That projects to an unacceptable rate of $12.1 million over five years.

OIG Recommendations

The report lists two recommendations, both of which CMS has accepted:

- Medicare contractors should recover the $66.3 million it improperly paid out for specimen validity testing; and
- CMS and its software contractors should go back to the drawing board and come up with a better system edit solution for flagging improper billing of specimen validity tests in combination with urine drug tests edits to repair the leakage in the current edits.

Impact on You

If yours is among the 4,480 labs and physician offices to receive improper payments for specimen validity tests during the audit period, you can expect a repayment request from your Medicare contractor. But the recovery process may not be so simple and straightforward. True, your contractor knows who you are since the OIG audit identifies the improper payment recipients. The problem, at least for the contractors, is that the audit looks only at specific claim lines. As a result, contractors will have to conduct medical review of the entire claim to determine whether it includes a relevant diagnosis code.

OIG Work Plan Monthly Review: March 2018

One of the seven new items on the OIG's Work Plan this month, one deals with child support. Among the six items focusing directly on health care, none directly address clinical laboratories or diagnostic testing. However, a few labs may be indirectly affected by some of the new items depending on the services they provide, school program testing, and programs in which they participate, e.g., Indian Health Services.

1. Medicare Part D Opioid Use Data Brief

Issue: Of the 52,000 drug overdose deaths in the US in 2015, over 33,000 involved opioids. In 2016, the problem got worse with over 175 drug overdose deaths per day.

OIG Action: The OIG plans to create a data brief providing updated data on Part D spending for opioids, the number of beneficiaries receiving ex-

treme amounts of opioids through Part D and the number of beneficiaries who appear to be "doctor shopping."

2. ACL Oversight of Independent Living Programs

Issue: As part of the Administration for Community Living (ACL) sponsorship of nationwide programs supporting independent and community living for people with disabilities. Among its other oversight responsibilities, the ACL conduct onsite compliance reviews of at least:

- 15% of Centers for Independent Living that receive funding under Title VII of the Rehabilitation Act of 1973; and
- One-third of designated State units that receive funding under the Act.

OIG Action: The OIG will review the ACL's plan for compliance with the onsite review requirements and ACL oversight activities for monitoring independent living programs.

3. Compliance with Grantee Cost Principles by Organizations with Multiple HHS Discretionary Funding Sources

Issue: HHS grantees are required to maintain financial management systems that contain written procedures for determining the reasonableness, allocability and allowability of costs in accordance with applicable federal cost principles and the terms and conditions of the award, as well as accounting records supported by source documentation.

OIG Action: The OIG plans to review select grantees receiving HHS grant funding from multiple sources to determine whether they are allocating and claiming costs in accordance with federal requirements and review current HHS procedures for oversight and coordination between the participating grant programs.

4. Adverse Events in IHS Hospitals

Issue: The Indian Health Service operates 26 hospitals offering free inpatient care to eligible American Indians and Alaska Natives, many of which are located in remote areas and have low average daily patient censuses.

OIG Action: The OIG will identify adverse and temporary harm events at IHS hospitals in FY 2017 and estimate the incidence and preventability of these events by reviewing medical records associated with a sample of inpatient stays. It will also assess the extent to which IHS hospitals recorded these events in their incident reporting systems.

5. Financial & Administrative Review by IHS Area Offices

Issue: Congress has expressed concern about IHS's administrative and financial management of program funds to provides health services to approximately 2.2 million American Indians and Alaska Natives in 567 federally recognized Tribes located in 35 states. These services are funded through annual appropriations distributed among IHS headquarter offices and 12 regional offices called Area Offices. These services are provided through IHS and Tribal facilities that operate (1) IHS direct health care service programs, (2) tribally operated health care service programs authorized under Titles I and V of the Indian Self-Determination and Education Assistance Act (P.L. No. 93-638), and (3) Urban Indian Health Program services and resource centers.

OIG Action: The OIG will examine how an IHS Area Office monitors and allocates appropriations received from IHS headquarter offices within its geographic area and examine an Area Office with respect to accounting for IHS annual appropriations and allocating IHS appropriations to service units within the Area Office's geographic area.

6. Medicaid School-Based Costs Claimed Based on Contingency Fee Contractor Coding

Issue: During a previous review, the OIG found that one consultant of a state Medicaid agency paid a contingency based on the percentage of federal funds reimbursed to the state developed unsupported time studies that it used to develop payment rates for school-based health services. Based on those rates, the state claimed unallowable federal funds. Consultants in many other states also developed time studies using a similar methodology.

OIG Action: The OIG will do a multiple state review with a roll-up report to CMS to determine whether consultants developed school-based Medicaid rates based on unsupported time studies and unallowable costs in those states.

Theranos & Its CEO Settle Stock Fraud Charges with SEC

- CMS;
- The Arizona Attorney General;
- Walgreen's;
- Its own shareholders.

And now Theranos has a new legal adversary: the US Securities Exchange Commission which has charged Theranos and its founder and CEO, Elizabeth Holmes with securities fraud for allegedly making false claims about its prickless blood analyzing technology to raise over $700 million in investment capital.

The Settlement Deal

On March 14, we learned that the company and Holmes have settled with the SEC. Under the settlement, Holmes will pay a $500,000 penalty, disgorge the 18.9 million shares in Theranos stock allegedly acquired via the fraud, and give up her voting control over the company. Holmes has also been barred for serving as an officer or director of a publicly traded company for 10 years.

According to the SEC, the defendants knowingly made false claims including predicting that the analyzer would generate over $100 million in 2014 revenues. Actual revenues came in just $99.9 million short of those projections. The SEC also charged the defendants with claiming that the product was used on the battlefield in Afghanistan and in medevac helicopters, neither of which was true.

Not included in the settlement is Theranos's former President Ramesh Balwani who will get the chance to prove his innocence in a US California District Court.

Case of the Month: $11.4 Million Natera Settlement Shows Genetic Billing & Coding Remains a False Claims Hot Button

Before the opioid crackdown, false billing of genetic tests was the hottest thing in federal fraud enforcement against clinical labs. But while drug testing related to prescription opioids has stolen the spotlight (See *GCA* March 2018, for more), the recent case involving one of the nation's leading firms serves as a reminder that genetic testing remains very much on the radar of the DOJ and whistleblowers.

Sequencing-Based Prenatal Screening

Current treatment guidelines recommend offering prenatal screening to *all* pregnant women in the early stages of gestation to detect fetal aneuploidy, i.e., the presence of an abnormal number of chromosomes in a cell. Two types of noninvasive, sequencing-based testing are commercially available for detecting fetal cell-free DNA fragments in maternal serum:

- Next-generation sequencing-based quantitative tests; and
- Targeted amplification tests capable of detecting single nucleotide polymorphisms (SNP), i.e., variations in a single base pair in one DNA sequence on targeted chromosomes in a single reaction.

The Suit against Natera

One of the leading SNP prenatal tests is Panorama, an assay produced by Silicon Valley-based Natera capable of detecting not only relatively common conditions involving extra genes associated with disorders like Down's Syndrome but microdeletions which are harder to detect and much rarer.

Natera's billing of Panorama was at the center of a significant new fraud case. It began when a pair of ex-Natera employees who worked with providers in administering follow-up tests detected by screening with Panorama filed a *qui tam* whistleblower lawsuit. Among other things, they claimed that Natera used a CPT code for DNA and chromosome analysis which the Medicaid, TRICARE and the Federal Employee Health Benefits cover instead of an SNP-based testing code which they do not cover to bill for the screenings. The government decided to intervene, charging Natera with $80 million in false billings over a four-year period.

The Settlement

Natera vigorously denied the allegations. But rather than risk a trial, Natera decided to settle the suit for $11.4 million, 19.6% of which will go to the whistleblowers. The terms:

- $5.3 million upfront;
- $5.3 million plus interest in four quarterly installments; and
- $756,183 to state Medicaid programs.

The settlement is also notable for what it did not include, namely an admission of guilt or a corporate integrity agreement. The absence of the latter is an indication that the government considered the alleged wrongdoing to be more mistake than malice.

Takeaway: False billing of genetic testing will remain a significant area of concern for lab compliance going forward (See the SCORECARD below). Adding to the challenge is that testing moves faster than billing and coding. Indeed, after the settlement Natera officials offered a plausible explanation of what went wrong, noting that when it first launched Panorama it had sought the advice of a "nationally recognized coding expert" for billing advice since there was no assay-specific code for the test at the time. (Now such a code does exist—CPT 81420.) And to the extent your lab bills for a newly emerging test that does not have its own CPT code, you face the same conundrum.

SCORECARD: Leading Whistleblower Suits for False Billing of Genetic Tests

CASE	STATUS/OUTCOME	ALLEGATIONS
Millennium Laboratories	$256 million settlement, 2015	False billing and paying kickbacks for referrals of medically unnecessary genetic tests provided to pain management patients
21st Century Oncology	$24.86 million settlement, 2015	False billing of medically unnecessary FISH tests to detect genetic abnormalities associated with bladder cancer
Bostwick Laboratories	$6 million+ settlement, 2015	False billing of medically unnecessary FISH tests to detect genetic abnormalities associated with bladder cancer
Pathway Genomics	$4.036 million settlement, 2016	Paying kickbacks for referrals of genetic tests
Prestige Healthcare	$1 million settlement, 2017	False billing genetic tests for nursing home patients that were not medically necessary or without a physician's order
Proove Biosciences	Still pending	False billing and paying kickbacks for referrals of medically unnecessary genetic tests provided to pain management patients

Happy Endings: Guardant & Foundation Make Sweet Lemonade Out of False Advertising Lemons

In June 2017, Guardant Health sued Foundation Medicine for making false statements about the Guardant360 test in its advertisements for the FoundationACT liquid biopsy genomic profiling test. Foundation denied the allegations and countersued, claiming that Guardant was the one making false statements about the tests in its advertising materials. But now cooler heads have prevailed with news that the sides have settled the case by asking that both claims be dismissed.

But what makes the settlement worthy of inclusion in this column are the proactive measures the sides agreed to take to turn an ugly situation into a positive, including the creation of:

- A process to quickly resolve any future advertising-related disputes between the companies; and
- A working group to study development of standard definitions and formulas validating genomic profiling assays.

Brief Your CEO: The New CMS Appeals Process & How to Use It to Get Medicare to Pay, From Page 1

- Beneficiaries, enrollees, their family members or estates;
- State Medicaid Agencies;
- Medicare Advantage Organizations (Medicare Part C); and
- Those that have filed for or expect to file for bankruptcy.

Assuming you determine that your lab is eligible, prepare your CEO briefing and make sure it includes the following five points about the LVA process:

1. The Potential Upside

Start out by explaining what is nearest and dearest to the heart of any executive: the value proposition to your lab. Explain that Medicare payment appeals tend to be time-consuming and costly, not to mention risky. The advantage of the new LVA settlement process is that it offers timely—albeit partial—payment of 62% of the net Medicare approved amount.

2. Which Appeals Are Eligible

Continue by noting that appeals must meet all seven of the following criteria to be eligible for LVA settlement:

- ☐ The appeal was pending before the Office of Medicare Hearing and Appeals (OMHA) and/or Council level as of Nov. 3, 2017;
- ☐ It was properly and timely at the OMHA or Council levels as of Nov. 3, 2017;
- ☐ The appeal is still pending as of the date the LMV agreement is signed (as explained in the Settlement Process section below);
- ☐ The appeal's total billed amount is $9,000 or less;
- ☐ The claims in the appeal were denied by a Medicare contractor and remain in a fully denied status within the Medicare system;
- ☐ The claims were submitted under either Medicare Part A or B; and
- ☐ The claims are not part of an extrapolation.

3. The All-or-Nothing Condition

Note that if your NPI is approved for participation in the LVA process, the resulting settlement covers all eligible appeals from you. In other words, the appellant is not allowed to choose to settle some eligible appeals but not others.

4. The Settlement Process

The heart of your briefing should be a discussion of the detailed procedural rules your lab must follow to use the LVA process.

First Step: EOI Submission

It is up to your lab, the appellant, to initiate the process by filing a form called a Low Volume Appeals Settlement Expression of Interest (EOI) to CMS at MedicareAppealsSettlement@cms.hhs.gov during the appropriate window, based on your NPI.

EOI Submissions Windows

Appellants Designation	EOI Window
Appellants with NPIs ending in even numbers (including 0)	Feb. 5, 2018 to March 9, 2018
Appellants with NPIs ending in odd numbers	March 12, 2018 to April 11, 2018

Labs with multiple NPIs must submit one EOI per NPI with eligible appeals during the appropriate window depending on whether the NPI ends in an odd or even number.

Second Step: Determination of Participation Eligibility

CMS must review the EOI to determine if you are eligible to participate in the LVA process. If so, it will send you:

- A Spreadsheet of potentially eligible appeals and associated claims; and
- An Administrative Agreement.

Third Step: Validation & Signing

You must next review the Spreadsheet and either validate it or notify CMS of any discrepancies you identify by submitting an Eligibility Determination Request (EDR) form to MedicareAppealsSettlement@cms.hhs.gov within 15 days of receiving the Spreadsheet. If there are no discrepancies, you must also sign the Agreement and send it to CMS for counter signing; if there are discrepancies, Step 4 comes into play.

Fourth Step: Reconciliation

You have 30 days to resolve any identified Spreadsheet discrepancies with CMS. When and if that happens, you must sign the Agreement and send it to CMS for counter signature. Once CMS counter signs, whether via Step 3 or 4, it will send you a copy of the fully executed Agreement.

Fifth Step: The Withdrawal Right

Conclude by reassuring the executives that if you get cold feet about using the LVA to settle your lab's pending appeals, you may withdraw from the process and retain full appeal rights, as long as you have not yet returned the signed Agreement to CMS. But once CMS gets the signed Agreement from you, it will "stay," i.e., freeze proceedings on all of your pending appeals and there will be no turning back.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

No Dice for Whistleblower Claim Blaming Software Firm for Double-Billing

Case: A physician coding supervisor for a North Carolina health system that used billing software from Epic filed a *qui tam* lawsuit against the firm claiming that the product caused it to double-bill the government for "hundreds of millions of dollars" worth of anesthesia services. The government declined to join the case and the district court judge in Florida tossed it out without a trial [*US ex rel. Petrowski v. Epic Systems Corp.*].

Significance: The whistleblower's legal problems stemmed less from the claim's substantive merits—or lack thereof—but the amateurish and ineffective way in which it was asserted. The judge chastised the whistleblower for merely parroting language from the *False Claims Act* and failing to provide specific, credible allegations of how Epic had violated it. To make matters worse, she didn't try to amend and clarify the complaint even after Epic moved to have it dismissed due to vagueness and lack of specificity. But the whistleblower is considering her appeal options and the case may not yet be over.

Vermont Hospital Accused of Falsely Billing Outpatient Tests Settles for $1.65 Million

Case: The DOJ contended that between 2012 and 2014 Brattleboro Memorial Hospital (BMH) knowingly submitted claims for outpatient lab tests without the required medical necessity documentation. "In some instances, the clinicians' orders for laboratory tests did not appear to adequately document the diagnosis code included on the billing claim form as required," according to the U.S. Attorney. Rather than risk a trial, BMH coughed up $1,655,000 to settle the case.

Significance: BMH likely avoided a much higher fine by fully cooperating with the investigation and implementing billing system and personnel changes to address the problem that led to the improper billing. The bad news is that BMH might have been able to prevent the case from being brought in the first place had it heeded the warnings of the veteran administrator in the finance department who allegedly observed the billing improprieties. But after her "vigorous protests" went ignored and she began experience what felt like recriminations, she went the legal route by filing a *qui tam* whistleblower lawsuit against BMH. The government joined the suit, all but forcing the settlement and the whistleblower will share 15% to 20% of the recovery.

Doctor Busted for Drug Test Abuses as Part of "Pill Mill" Scam

Case: Dr. Rodney Moret, a 67-year-old Michigan M.D, pleaded guilty to using his pain management and HIV infusion clinic as a "pill mill." In addition to illegally dispensing $15 million worth of prescription drugs, including controlled substances Hydrocodone, Alprazolam, and promethazine with codeine cough syrup, the doctor billed Medicare for $6 million worth of tests that were either not medically necessary or not performed at all. Sexually molesting and harassing female patients made an ugly situation that much more hideous and surely weighed in the judge's decision to sentence the doctor to 75 months' imprisonment.

Significance: Dr. Moret is the most recent doctor taken down in what has become a crucial part of the federal government's opioid drug crusade: urine tests ordered by prescribing physicians to be performed at the labs they own. (See *GCA* March 2018, for more details.)

Drug Testing Lab & Referring Psychiatrist Indicted for Kickbacks

Case: After a lengthy investigation, the feds indicted the owner of a now-defunct Kentucky clinical drug testing and screening lab for allegedly paying $843,242 to a psychiatrist in illegal kickbacks for Medicaid patient referrals. The psychiatrist was also indicted.

Significance: Each defendant faces a maximum sentence of $250,000 in fines and/or five years in jail. The lab owner denies the charges citing his 50+ years of sanction-less service; the psychiatrist has yet to respond.

Precipio Inc. Settles Shareholders' Suit for $1.9 Million

Case: Crede Capital Group invested $5 million in Transgenomic in exchange for stocks and warrants. In June 2017, Transgenomic merged with molecular DX firm Precipio and the surviving company, Precipio Inc., assumed Transgenomic's debts. Crede then exercised its Transgenomic warrants. But when Precipio Inc. allegedly did not make the required cash payments and Crede sued for $2 million in damages. Rather than fight it out in court, the parties have agreed to settle the case for $1.925 million in cash, stock or a combination of both to be paid out over a 15-month period.

Significance: The settlement is just one of the things the newly merged firm has done to reduce Transgenomic's roughly $19+ million pre-merger debt to $7 million. News of the debt reduction, which was included as part of Precipio Inc.'s most recent Securities Exchange Commission public filing, sent shares up nearly 30% to $.66.