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Reimbursement: OIG Medicare Lab Spending Report May Warn of Greater Scrutiny of Genetic and Automated Chemistry Tests

PAMA and market-based rate reductions for lab testing was supposed to save Medicare bundles of money. But according to a new OIG report, Medicare Part B spending on lab spending for 2018, the first year of the new PAMA pricing scheme, actually increased. Not only that, but the increase was the biggest since PAMA was passed in 2014.

The OIG's Findings

As the PAMA law requires, the OIG analyzed 2018 claims data for tests reimbursed under the Part B Clinical Laboratory Fee

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Enforcement Trends: Granston Memo Whistleblower Dismissals May Be Tougher than DOJ Thought

In 2018, the Justice Department sent an internal memorandum ordering US Attorneys to aggressively seek to dismiss False Claims Act (FCA) whistleblower qui tam lawsuits that lack merit or don't serve the government's interests. But a new case from federal appeals court for the Ninth Circuit suggests that targeting whistleblower suits for dismissal won't be as easy as the DOJ might have expected.

The FCA's Little-Used Liquidation Provision

Under the FCA, whistleblowers (aka "relators") suing companies for submitting false claims to the federal government must be filed under seal to give the DOJ time to decide whether to intervene in the case. Relators can still go forward with the case if the DOJ declines to intervene. But at that point, their leverage in settlement negotiations significantly declines and their risks in taking the case to court significantly increases.

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Reimbursement: OIG Medicare Lab Spending Report May Warn of Greater Scrutiny of Genetic and Automated Chemistry Tests, *from page 1*

Schedule (CLFS) in comparison to 2017 CLFS spending. Results: Even though 75 percent of the tests were subject to the PAMA fee cuts, Medicare spending on CLFS lab testing increased $459 million, from $7.1 billion in 2017 to $7.6 billion in 2018. In other words, the rate cuts weren't enough to offset the increased spending for other tests, including:

... the OIG suspected foul play and called for more oversight over genetic tests, particularly molecular pathology tests which accounted for 50 percent of all Medicare genetic test expenditures. "Even a small number of inappropriate tests could expose Medicare to extremely high spending," the agency warned.

Genetic tests, which went from $473 million to $969 million as a result of higher utilization and the addition of new and expensive tests to the CLFS. Spending on genetic tests increased to $969 million from $473 million due to new and expensive tests entering the fee schedule and an increase in volume of existing genetic tests, the report said. According to the OIG, total spending on genetic tests increased to 13 percent of Medicare spending for lab tests in 2018, versus 7 percent in 2017. Claims for genetic tests increased from 950,000 units to 1.76 million and the number of tests that Medicare reimbursed increased to 199 from 110.

Automated chemistry tests, which increased by $82 million due to the removal of a previous discount on the tests that was no longer allowed under PAMA.

In explaining the spending increases, the OIG also cited the one-time increases resulting from spending on tests for which the national rate was actually higher than the local payment rates it replaced. That bump was due to the transition to the new system and won't recur.

Takeaway

As it usually does when it comes to spending for lab tests, the OIG suspected foul play and called for more oversight over genetic tests, particularly molecular pathology tests which accounted for 50 percent of all Medicare genetic test expenditures. "Even a small number of inappropriate tests could expose Medicare to extremely high spending," the agency warned.

The OIG also recommended that CMS "seek legislative authority to establish a mechanism to control costs for automated chemistry tests." While indicating that it "neither agreed nor disagreed" with the recommendation, CMS said it would "monitor utilization and spending associated with these codes" and consider OIG's advice in determining what to do next.

LCA

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Labs IN COURT

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

NIPT Lab Company Pays $49 Million to Settle False Billing and Kickback Charges

Case: A month after going public, Progenity agreed to shell out $49 million to settle claims of overbilling and paying physicians kickbacks to order its noninvasive prenatal tests (NIPT). The case, which began as a whistleblower lawsuit, contends that the San Diego biotechnology knew the test performed wasn't FDA approved, and thus not covered by TRICARE; as a result "it falsely and fraudulently used a medical billing code that TRICARE did cover." The settlement also resolves claims of falsely billing Medicaid for NIPT with state attorneys general getting $13.2 million of the sum.

Significance: In addition to deliberately using a false billing code, prosecutors accused Progenity of kickback violations, including:

- Paying physicians excessive "draw fees" above fair market value for collecting blood specimens for the NIPT tests;
- Providing meals and happy hours disguised as educational sessions for physicians and their staff; and
- Improperly waiving or reducing patient coinsurance and deductible payments.

Whistleblower Can Sue Lab for Alleged Specimen Fee Kickback Collection Ripoff

Case: A whistleblower filed a False Claims Act suit charging a California lab of entering into "sham phlebotomy contracts" paying kickbacks to physicians' family members and staff in the form of process, handling and collection fees at above market rates. The lab argued that the $15 per blood sample draw fees, as compared to the Medicare rate of $3, were legitimate because: (1) they covered a "panoply" of services that including apportioning the blood in vials, spinning the vials in a centrifuge, packaging and labeling the vials and arranging for shipment; (2) the $15 payment is made to a staff or family member and not to the physician. But the federal court denied the lab's motion to dismiss the case.

Significance: The ruling just means the case can go to trial and isn't a decision on the merits. In determining that the whistleblower had a legally valid FCA claim, the court cited the 2014 OIG Special Fraud Alert warning that the potential for paying kickbacks in the form of excessive collection fees extends not just to blood collections but other specimen processing and arrangements, in essence nixing the lab's "panoply" argument. As for whether $15 was a legitimate rate for the fees, the question at the dismissal stage isn't whether the charges are true but whether the complaint states a valid legal claim, assuming the charges are true. So, the lab would have to keep its price defense in its back pocket and use it at trial [*United States ex rel. STF, LLC v. Vibrant Am., LLC,* 2020 U.S. Dist. LEXIS 150345].

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Labs in Court: A roundup of recent cases and enforcement actions involving the diagnostics industry, *from page 3*

Connecticut Methadone Clinic Settles Urine Drug Test False Billing Charges for $345.3K

Case: A methadone clinic settled claims of overbilling the Connecticut Medicaid Program for urine drug tests for $354,367. Under state rules, methadone clinics receive a bundled weekly per patient rate that includes on-site drug abuse testing and monitoring. The case began when state auditors discovered that both the clinic and an outside independent lab billed Medicaid for testing performed by the latter in violation of the bundling rules, forcing the state to pay twice for the same test.

Significance: Apparently, this wasn't the clinic's first violation of the bundling rules. In 2016, the state issued an Audit Report cautioning the clinic about improperly referring urine drug tests to an outside lab and warning of financial disallowances in future audits if it continued. And it did continue.

Lab Sues Health Plan for Failing to Reimburse and Stonewalling on Pay Resolution

Case: Over the first two years of the contract, the health plan reimbursed the toxicology drug-testing lab promptly and in full. The problems began when the plan brought in an outside auditor which made medical records and documentation demands that the lab contended weren't simply onerous but also unreasonable. Soon thereafter, the plan stopped paying the lab's claims—adding up to $681,126 over a 10-month period. The lab made numerous attempts to resolve the payment disputes only to be met by a "shell game" of ever-shifting excuses ranging from lack of medical necessity to improper billing for presumptive and definitive testing of samples. So, the lab sued on half a dozen grounds, three of which the New York court dismissed.

Significance: The plan conceded that the breach of contract and state insurance law claims should be allowed to go to trial but contested the other four. When it was all said and done, the plan's batting average was .750, with the court tossing the lab's claims for declaratory judgment, violation of state General Business Law and tortious interference with business relations. The one claim that survived dismissal was for breach of good faith and fair dealing, which the court said wasn't duplicative of the breach of contract claim [*Truetox Labs., LLC v Healthfirst PHSP, Inc.*, 2020 N.Y. Misc. LEXIS 4058, 2020 NY Slip Op 50900(U), 68 Misc. 3d 1209(A)].

Compliance Perspectives: What, If Anything, Does OSHA Require You to Do to Protect Telecommuters?

While telecommuting is nothing new, the imperative for using it has never been greater. In addition to all the cost-saving, work-life balance, recruiting and hiring advantages, letting employees work from home during a pandemic has become a vital infection control measure. But it also poses significant compliance challenges, particularly in the realm of OSHA. After all, how are you supposed to meet your duty to protect the health and safety of lab employees if they work from home at a location beyond your physical control? This article will provide the answer.

Spoiler Alert: OSHA requirements don't generally extend to employees working from home; but you still can and should take some basic steps to ensure their health and safety.

OSHA & Telecommuters

The Occupational Safety and Health Act (Section 4(a)) applies to "employment performed in a workplace." Although the Act doesn't define "workplace," the case can be made that the concept includes any location in which employees perform job duties on a lab's behalf, including a home office.

OSHA addressed the issue in 1999 in response to a letter from a company CSC Credit Services asking what, if anything, it had to do to protect the health and safety of sales executives telecommuting from home. OSHA's answer: "Employers should exercise reasonable diligence to identify in advance the possible hazards associated with particular home work assignments, and provide the necessary training, PPE or other controls to reduce or eliminate the hazard." In some cases, that might require doing an on-site inspection of the telecommuter's workplace, OSHA added.

This wasn't the first time that OSHA had issued an advisory opinion suggesting that the law applied to home work sites. But it was the first time the opinion drew public attention. In January 2000, the Washington Post published an article about the letter and OSHA's position, detonating a firestorm of protest from the media, U.S. Chamber of Commerce, members of Congress and the White House.

Within days, the Department of Labor withdrew the letter. And on Feb. 25, 2000, OSHA issued guidance (Directive Number: CPL 2-0.125) to inspectors about worksites inside an employee's home. The guidance makes three key points:

- OSHA won't do inspections of employees' home offices;
- OSHA won't hold employers liable for employees' home offices; and
- OSHA doesn't expect employers to inspect the home offices of their employees.

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Compliance Perspectives: What, If Anything, Does OSHA Require You to Do to Protect Telecommuters?
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The Injury Reporting Caveat

Even though labs and other employers don't have liability or a duty to go into an employee's home office to do an inspection, they still have recordkeeping obligations for any work-related injuries or illnesses the employee suffers, regardless of whether they occur at the lab, in the home office or anywhere else. In a March 30, 2009 advisory letter, OSHA made it clear that "injuries and illnesses that occur while an employee is working at home, including work in a home office, will be considered work-related if they occur while the employee is performing work for pay or compensation in the home, and the injury or illness is directly related to the performance of work rather than to the general home environment or setting." OSHA also lists examples:

- **Work-related:** Employee drops a box of work documents and injures his/her foot;
- **Not work-related:** Employee is electrocuted at home because of faulty home wiring.

The Workers Comp Caveat

In addition to OSHA recordkeeping responsibilities, workers comp laws cover injuries and illnesses that "arise out of or occur during the course of employment." That would generally extend to injuries suffered by telecommuters while performing work functions in their home office, e.g., the foot injury caused by the employee's dropping a box of work documents listed above.

How to Protect Telecommuters

So, it comes down to this. OSHA requires you to track, record and report the work-related illnesses and injuries suffered by telecommuters while they're working from home; but it doesn't require you to take any special measures to prevent those illnesses and injuries. Of course, there's more to life than OSHA. In addition to being a moral duty, protecting telecommuters enables you to avoid workers comp claims, productivity losses and other costs associated with employee injuries and illnesses.

If you are prepared to go the health and safety route, require lab employees seeking approval to telecommute to designate a room or area as their home workspace. Then, somebody should perform a hazard assessment inspection to verify that the workspace is:

- Appropriate for the work;
- Well lit;
- Properly ventilated;
- Free of obstructions and trip and fall hazards;

- Equipped with appropriate first aid supplies and equipment;
- Free of biohazards and other hazardous materials;
- Free of electrical hazards;
- Secure;
- Ergonomically safe; and
- Compliant with fire and building codes.

There are three ways to go about performing the hazard assessment:

- **Option 1:** Have a lab supervisor or manager visit the site and do a physical walk-through inspection;
- **Option 2:** Have the employee videotape the space and/or submit detailed photos and a floor plan and do the inspection virtually;
- **Option 3:** Have the employee inspect the space himself/herself.

While Option 1 is most likely to provide accurate and meaningful results, it's also the most privacy-invasive and could raise liability issues. Best Practice: In any event, have the person who does the assessment use the Telecommuter Home Office Hazard Assessment and Inspection Checklist **(see model checklist below)**.

Injury and Incident Reporting

One final loose end: Require employees who work from home to immediately notify their supervisors of any injuries or safety incidents that occur in their workspace, just the way they'd have to do for work incidents at the organization's own facilities. Employees should also provide you either access to the space or the information you need to maintain OSHA Logs for their work injuries and illnesses.

TOOL

Telecommuter Home Office Hazard Assessment & Inspection Checklist

While not an OSHA obligation, it's highly advisable to take measures to protect the health and safety of telecommuting lab employees who work from home. How? By having employees seeking approval to telecommute designate a room or area as their home workspace and arranging for somebody to perform a hazard assessment inspection to verify that the workspace is safe, healthy and appropriate for the proposed use.

- **Option 1:** Have a lab supervisor or manager visit the site and do a physical walk-through inspection;
- **Option 2:** Have the employee videotape the space and/or submit detailed photos and a floor plan and do the inspection virtually;
- **Option 3:** Have the employee inspect the space himself/herself.

Whoever does the assessment should use the Checklist below.

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Model Tool: Telecommuter Home Office Hazard Assessment & Inspection Checklist, *from page 7*

Telecommuter Home Office Hazard Assessment & Inspection Checklist

ITEM TO CHECK	YES	NO	COMMENTS
SAFETY OF GENERAL WORK ENVIRONMENT			
Floors are free of obstructions and slip/trip/fall hazards			
Aisles, doorways and corners are free from obstructions to permit movement			
Workspace is kept in a clean and sanitary condition			
Workspace is well lit			
Workspace is adequately ventilated			
Workspace is well heated and air-conditioned			
Phone lines and cords are secured along a wall and away from heat sources			
Computer to be located in secure location that minimizes risk of unauthorized access, theft and damage			
Adequate first aid supplies are readily available			
Workspace is reasonably quiet and free of distractions			
Home has been tested for radon			
Workspace is free of biohazards, hazardous chemicals and other hazardous products			
FIRE SAFETY			
Walkways, aisles and doorways are unobstructed			
Working smoke detector covers the designated work space			
Charged, accessible fire extinguisher is in the area			
There's more than one exit from the workspace			
Workspace is kept free of trash, clutter and flammable liquids			
All radiators and portable heaters are located away from flammable items			
Storage is organized to minimize risks of fire and spontaneous combustion			

ITEM TO CHECK	YES	NO	COMMENTS
ELECTRICAL SAFETY			
Computer equipment is connected to a surge protector			
Electrical system is adequate for office equipment			
All electrical plugs, cords, outlets and panels are in good condition with no exposed/damaged wiring			
Electrical enclosures (switches, outlets, receptacles, junction boxes) have tight-fitting covers or plates			
Extension cords and power strips aren't daisy chained			
No permanent extension cords are in use			
Electrical cords run in non-traffic areas, don't run under rugs and aren't nailed or stapled in place			
Equipment is turned off when not in use			
Electrical outlets are grounded with 3-pronged plugs			
WORKSTATION ERGONOMICS			
Desk is an appropriate height			
When keying, worker's forearms are close to parallel with the floor			
Monitor is 20-24 inches from eyes and top of screen is slightly below eye level			
Chair is sturdy and adjustable with backrest and casters appropriate for floor surface			
Chair is adjustable and worker knows how to adjust it			
Worker's feet reach the floor when seated or are fully supported by a footrest			
Worker's back is adequately supported by a backrest			
Computer screen is free from noticeable glare			
There's adequate lighting at the workstation			

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Model Tool: Telecommuter Home Office Hazard Assessment & Inspection Checklist, *from page 9*

ITEM TO CHECK	YES	NO	COMMENTS
EMERGENCY EVACUATION/RESPONSE			
There's an appropriate evacuation plan in place			
Emergency contact information is posted in a conspicuous location			
Appropriate emergency communications equipment is in place			
OTHER SAFETY/SECURITY MEASURES			
Files and data are secure			
Materials and equipment are in a secure place that can be protected from damage or misuse			
There's inventory of all equipment in the office, including serial numbers when possible			

COMMENTS: Indicate whether any other health and safety hazards are apparent or measures are necessary for the workspace:

Quiz: Can Racial Discrimination Be Proven with Circumstantial Evidence Alone?

SITUATION

An equipment repair technician who also happens to be the lab's only African American employee endures racial abuse at the hands of his supervisor and co-workers. He complains to management and is warned to "stay in his lane." Shortly thereafter, somebody leaves a noose on his desk. It's the last straw. The technician claims he was subject to systemic racial discrimination and files an EEOC complaint. The lab closes ranks and vehemently denies the charges and nobody is willing to testify on the technician's behalf. Without witnesses to corroborate his story, the technician is left to rely on the following evidence:

- Pictures of the noose on his desk;
- His own testimony, which is credible and reliable; and
- The fact that the lab manager and supervisor's denials lack credibility and consistency.

QUESTION

Can the technician prove the lab committed racial discrimination?

A. No, because he has no witnesses other than himself

B. Yes, to the extent his circumstantial evidence is strong and believable

C. No, because there's no direct evidence that racial discrimination occurred

D. Yes, because being the lone African-American employee is proof of discrimination

ANSWER

B. It's possible for the technician to prove racial discrimination relying only on circumstantial evidence

EXPLANATION

Employees and job applicants claiming discrimination have the burden of proving that they experienced disadvantage, unequal or adverse treatment because they have a characteristic protected by discrimination laws, e.g., racial harassment at work because they're African American. This scenario illustrates the evidence employees can use to meet that burden of proof.

Direct evidence such as video or credible and reliable first-hand eye-witness testimony carries the most weight because, as its name suggests, it proves the charge directly without need of further evidence or presumptions. The problem is that direct evidence isn't available in many, if not most racial discrimination cases. People who engage in racist conduct are typically careful to cover their tracks. Often, there are no witnesses, or at least no witnesses willing to testify on the employee's behalf.

Indirect evidence, aka circumstantial evidence, proves the charge on the basis of other proven facts, e.g., that a person proved to have used a racial epithet on previous occasions also used the same epithet in the case at issue. Although it's not as powerful as direct evidence, courts allow alleged victims to use circumstantial evidence to prove their charges.

But circumstantial evidence must also be convincing. It often boils down to which side is more credible. In this case, the technician's account is more credible and reliable than the manager and supervisor's denials.

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Quiz: Can Racial Discrimination Be Proven with Circumstantial Evidence Alone?, *from page 11*

Coupled with pictures of the noose on the desk, which indicate that acts of racism did occur in the workplace, give the technician an excellent chance to prove his racial discrimination claims. So, B is the right answer.

WHY WRONG ANSWERS ARE WRONG

A is wrong because racial discrimination is often unwitnessed and the victims are the only ones who can testify on their own behalf.

C is wrong because direct evidence of racial discrimination is relatively rare; that means victims must be allowed to rely on circumstantial evidence to have any chance of proving their claims.

D is wrong because, while the fact that a company has just one minority employee may be circumstantial evidence of discrimination, it's not nearly enough to prove it. The victim would need much more and stronger circumstantial evidence to make out a case of discrimination.

In the News: Healthcare Organizations Call for Quick Action on Kickback Law Changes

Labs and the health industry have been waiting for years for some Stark Law and Anti-Kickback Statute (AKS) relief. Last October, HHS, CMS and the OIG finally unveiled the long-awaited plans to modernize the laws and loosen their restrictions to allow for value-based care arrangements. (For the details, see *Lab Compliance Advisor* (*LCA*), Oct. 22, 2019). Then came the COVID-19 pandemic. And now comes word of still another roadblock. It seems that the final rules are bogged down in the White House Office of Management and Budget (OMB) and it's unclear when they'll be released.

On Aug. 5, a group of 120 healthcare organizations, trade groups, suppliers and vendors issued a letter asking the President to take fast action and approve the proposed changes. "With the completion of this important work so close at hand, a single word from you would lift your team across the finish line," the letter urges.

■ Enforcement Trends: Granston Memo Whistleblower Dismissals May Be Tougher than DOJ Thought
From Page 1

But it could get a lot worse for relators. That's because the government has the authority to do more than simply decline to intervene in the case. Section 3170(c)(2)(A) of the FCA allows the government to actually seek to have the case dismissed if it thinks the suit doesn't serve its interests. Historically, though, the DOJ rarely seeks dismissal under Section 3170(c)(2)(A).

The Granston Memo

But that all changed in January 2018, when DOJ Civil Fraud Section Director **Michael Granston** issued an internal memorandum instructing US Attorneys to be more aggressive in exercising their Section 3170(c)(2)(A) powers, which the Memo describes as crucial in enabling the agency to perform its "gatekeeper role" in preserving enforcement resources, protecting government interests and preventing weak cases from resulting in adverse judgments that weaken government enforcement powers. The Memo goes on to outline seven kinds of problematic *qui tam* claims that US Attorneys should target for dismissal:

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, e.g., *qui tam* actions that may compromise classified information, involve intelligence agency operations or military contracts.
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.

New Case Tosses Cold Water on *Qui Tam* Dismissals

For the past two years, US Attorneys have been following their marching orders and seeking dismissals of *qui tam* cases under Section 3170(c)(2)(A). Even though it's not a healthcare case, the Ninth Circuit ruling is

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Enforcement Trends: Granston Memo Whistleblower Dismissals May Be Tougher than DOJ Thought, *From Page 13*

significant because it's among the first to test the limits of the Granston Memo policy.

The case reached the Ninth Circuit after the lower court denied the government's motion to dismiss the *qui tam* suit of a relator accusing a mortgage lender of submitting false claims to the Federal Housing Administration (FHA). Denial was unwarranted, the Northern District of California court held, because the government failed to:

- Demonstrate a valid governmental purpose for dismissal; and
- Fully investigate the allegations of the complaint.

The government appealed the ruling on technical jurisdictional grounds, but the Ninth Circuit wouldn't budge. (United States v. United States ex rel. Thrower, No. 18-16408 (9th Cir. 2020).

What It Means

For better or for worse, the Thrower case represents a setback to the Granston Memo policy to the extent it indicates that courts may not be so willing to give the government unfettered discretion to get *qui tam* cases tossed out under Section 3170(c)(2)(A). The really troubling part for prosecutors is the "fully investigate" requirement, which imposes a new and potentially costly administrative burden on enforcement resources, precisely what the Granston Memo "gatekeeping" mandate seeks to avoid.

Takeaway

What makes the "fully investigate" pill even harder for prosecutors to swallow is how the case actually unfolded. At first, the DOJ just declined to intervene. The decision to seek dismissal came later after the relator amended her claim. In other words, the claim the DOJ wanted tossed out of the court wasn't the same claim it reviewed in declining to intervene. So, now it would have to do a new investigation. The concern is that relators with lousy or harmful cases will be able to tie the DOJ in knots and evade Section 3170(c)(2)(A) dismissal simply by amending their claims. But while this is the first challenge to the Granston Memo policy, the Thrower case will definitely not be the last.