

Reproduced with permission from BNA's Health Care Fraud Report, BNA Insights, 03/19/2014. Copyright © 2014 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

## Frontline of Health-Care Defense: Building Credibility for Corporate Counsel in Fraud Investigations



BY KIRK OGROSKY, MARILYN MAY, AND NORA SCHNEIDER

### I. Introduction

The Department of Justice and the Department of Health and Human Services Office of Inspector General began 2014 on the heels of a historic year of wide-ranging enforcement activity, notable settlements, and lengthy prison sentences for individuals.<sup>1</sup>

<sup>1</sup> DOJ obtained a \$237 million FCA judgment based upon Stark law violations against not-for-profit South Carolina-based Tuomey Health Care System Inc. If affirmed, the Tuomey judgment will be the largest Stark based judgment in history. Press Release, Dept. of Justice, Justice Department Recovers \$3.8 Billion from False Claims Act Cases in Fiscal Year 2013 (Dec. 20, 2013), available at <http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html>. DOJ recovered one of the largest FCA settlements from an individual when dermatologist Steven Wasserman resolved allegations that he entered into an illegal kickback arrangement with Tampa Pathology Laboratory for \$26.3 million. *Id.* Abbott Laboratories Inc. paid \$1.5 billion to resolve allegations that it illegally promoted the drug Depakote to treat agitation and aggression in elderly de-

*Kirk Ogrosky is a partner, Marilyn May is senior counsel, and Nora Schneider is an associate in the White Collar Defense and FDA/Healthcare practice at Arnold & Porter LLP in Washington, DC. They can be reached at [Kirk.Ogrosky@aporter.com](mailto:Kirk.Ogrosky@aporter.com), [Marilyn.May@aporter.com](mailto:Marilyn.May@aporter.com), and [Nora.Schneider@aporter.com](mailto:Nora.Schneider@aporter.com).*

For 2013, DOJ reported \$2.6 billion in health-care fraud judgments and settlements and total recoveries of \$4.3 billion.<sup>2</sup> During 2013, DOJ reported that whistleblowers and their counsel received almost \$325 million from settlements in addition to legal fees.<sup>3</sup>

DOJ reported that health-care fraud recoveries in 2013 marked the fourth straight year of more than \$2 billion in annual recoveries.<sup>4</sup> Since 2009, total False Claims Act (FCA) settlements amount to approximately

mentia patients and schizophrenia when neither of these uses was approved as safe and effective by the FDA. *Id.* Amgen Inc. paid the government \$762 million, including \$598.5 million in False Claims Act recoveries, to settle allegations that it illegally promoted Aranesp, a drug used to treat anemia, in doses not approved by the FDA and for off-label use to treat non-anemia-related conditions. *Id.* In a *per curiam* decision of the 11th Circuit Court of Appeals issued in 2013, the 50 year prison sentence of Lawrence Duran, the owner of American Therapeutic Corporation (ATC), was affirmed with the judges writing “[t]he sentences are harsh, but the offenses were grave. So goes the world of crime and punishment.” *Non-published Opinion on file with author, available at* <http://www.justice.gov/opa/pr/2011/September/11-crm-1202.html>.

<sup>2</sup> Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2013 (February 2014) (2013 HCFAC Report), available at <http://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf>. The report claims that \$4,333,555,846 was collected by all government components: (a) \$2,855,836,718 to the Medicare Trust Fund, (b) \$1,153,525,089 to other government programs and agencies, and (c) \$324,194,039 to whistleblowers.

<sup>3</sup> *Id.*

<sup>4</sup> Press Release, Dept. of Justice, Justice Department Collects More Than \$8 Billion in Civil and Criminal Cases in Fiscal Year 2013 (Jan. 9, 2014), available at <http://www.justice.gov/opa/pr/2014/January/14-ag-020.html>; Press Release, Dept. of Justice, Justice Department Recovers \$3.8 Billion from False Claims Act Cases in Fiscal Year 2013 (Dec.

\$17 billion—almost half of the estimated FCA recoveries since the FCA’s enactment in 1863.<sup>5</sup> While the FCA has been referred to as Lincoln’s law for over 150 years,<sup>6</sup> it may one day be referred to as Obama’s law given the emphasis that the current administration is placing on its use.

As the government increasingly relies on whistleblowers to set its regulatory agenda in health-care markets, corporate counsel will find themselves addressing aggressive, and often specious, allegations. The unfortunate side-effect of relator driven priorities is a minefield of erratic and ill-conceived investigations that fail to advance governmental long-term regulatory goals.

Criminal cases are also on the rise, but the focus areas set by criminal prosecutors tend to be separate and apart from the plaintiff’s attorney driven FCA investigations. Regardless of the origin of the investigation, in-house corporate counsel must be prepared to effectively and efficiently address subpoenas and government inquiries.

Health-care fraud enforcement will continue to be a top law enforcement priority well beyond 2014. Attorney General Eric Holder recently said: “this Administration has never been more determined to move aggressively in protecting patients and consumers, bringing criminals to justice, and building on what’s already been achieved.”<sup>7</sup>

In 2009, the Health Care Fraud Prevention and Enforcement Action Team (HEAT) was created to increase

coordination and optimize utilization of enforcement tools. Coupled with the passage of the Affordable Care Act, HEAT has claimed responsibility for a record-breaking \$10.7 billion in recoveries in the last three years.<sup>8</sup>

---

**As the government increasingly relies on  
whistleblowers to set its regulatory agenda in  
health-care markets, corporate counsel will find  
themselves addressing aggressive, and often  
specious, allegations.**

---

HEAT is the first presidential cabinet level initiative to tackle health-care fraud, and it largely serves to focus attention on the work being done across governmental components. It is this focus that has allowed for the expansion of enforcement tools to fight fraud.

These tools include: (a) 20 percent to 50 percent increased recommended prison terms for health-care fraud offenses over \$1 million; (b) enhanced screening for providers and suppliers who pose a higher risk of fraud; (c) expanded authority to suspend payments; and (d) additional funding over 10 years to grow enforcement efforts.<sup>9</sup>

The health-care industry applauds DOJ’s and OIG’s stepped up efforts to root out real fraud, but many companies struggle to address investigations that arise from ill-conceived, overzealous bounty-hunting. Some of these investigations thwart managerial innovation, run counter to incentive structures openly encouraged by the Affordable Care Act, chill medical advancement, and have become a lamentable part of life for in-house counsel.

Given this environment, nothing is more important than understanding how to present and promote integrity and credibility during an investigation.

In the FCA context, companies find themselves in the unenviable position of having to convince DOJ and OIG that fraud did not occur—in essence, having to prove innocence—after government attorneys have spent years listening to plaintiff’s attorneys spin tales to get DOJ invested and committed to their cases.

**In-House Counsel Needs to Establish Credibility.** This article provides an overview of the investigatory process, provides insight into the meaning behind certain enforcement activities, and puts forward several suggestions for in-house counsel to consider when dealing

20. 2013), available at <http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html>.

<sup>5</sup> False Claims Act, ch. 67, 12 Stat. 696 (1863) (codified as amended at 31 U.S.C. §§ 232-235). The U.S. FCA is believed to be based on *qui tam* laws dating back to the middle ages in England. Charles Doyle, *Qui Tam: The False Claims Act and Related Federal Statutes*, Congressional Research Service (Aug. 6, 2009). In 1318, King Edward II allowed a 33 percent recovery share to individuals who won claims against officials who moonlighted as wine merchants. *Id.* “The HCFAC account has returned over \$25.9 billion to the Medicare Trust Funds since the inception of the Program in 1997.” *2013 HCFAC Report* at 1; see also Press Release, Dept. of Justice, Justice Department Celebrates 25th Anniversary of False Claims Act Amendments of 1986 (Jan. 31, 2012), available at <http://www.justice.gov/opa/pr/2012/January/12-ag-142.html>

(“[a]mong the top settlements the government has achieved since the passage of the 1986 amendments are the following, which include, in some cases, criminal and state civil recoveries: \$2.2 billion—J&J (2013); \$2.3 billion—Pfizer Inc. (2010); \$1.7 billion—Columbia/HCA I & II (2000 and 2003); \$1.4 billion—Eli Lilly and Company (2009); \$950 million—Merck Sharp & Dohme (2011); \$923 million—Tenet Healthcare Corp. (2006); \$875 million—TAP Pharmaceuticals (2002); \$750 million—GlaxoSmithKline (2010); \$704 million—Serono, S.A. (2005); \$650 million—Merck (2008); and \$634 million—Purdue Pharma (2007)).

<sup>6</sup> “The False Claims Act was originally passed by Congress during the administration of President Abraham Lincoln in 1863 to help the government recover federal funds stolen through fraud by U.S. government contractors. During the Civil War, the law was used to recover monies from unscrupulous contractors who sold the Union Army decrepit horses and mules in ill health, faulty rifles and ammunition, and rancid rations and provisions.” *Id.* (DOJ 25th Anniversary Press Release).

<sup>7</sup> Press Release, Dept. of Justice, Attorney General Eric Holder Speaks at Chicago Health Care Fraud Prevention Summit (Apr. 4, 2012), available at <http://www.justice.gov/iso/opa/ag/speeches/2012-ag-speech-120404.html>.

<sup>8</sup> Press Release, Dept. of Health and Human Services, Obama Administration Announces Ground-Breaking Public-Private Partnership to Prevent Health Care Fraud (July 26, 2012), available at <http://www.hhs.gov/news/press/2012pres/07/20120726a.html>.

<sup>9</sup> See <http://www.stopmedicarefraud.gov/aboutfraud/aca-fraud/index.html>. While Congressional budget battles undoubtedly impacted OIG and DOJ in 2013, the success of the fraud fighting efforts since 2009 will likely spur a return to increased funding in 2014-15 to both FCA and criminal enforcement agencies. See <http://www.publicintegrity.org/2013/07/01/12909/medicare-fraud-outrunning-enforcement-efforts>.

with DOJ and OIG. The fundamental takeaway is that in-house corporate counsel need to establish credibility with the key agents who control and guide the investigation.

Building credibility with the government does not mean appeasement. It requires counsel to follow the law, stick to your word, act in good faith, communicate openly and honestly, and avoid gamesmanship.

Counsel who lose credibility with the government draw added scrutiny, whereas those who establish credibility ultimately receive the benefit of the doubt. This is especially true in the long run, but is also important during initial encounters when enforcement has a truncated view of the evidence. It goes without saying, but the way most attorneys damage their credibility with DOJ and OIG is by not having a grasp of the facts underlying the investigation.

After understanding the enforcement process, the first step for company counsel is to understand the facts.<sup>10</sup> It is worth noting that every investigation is unique and there is no single recipe for success. There are, however, basic principles that can help companies build credibility while addressing subpoenas, interview requests, and civil investigative demands. Finally, while the government might want to hide the ball in tough cases, they are better served by sharing information.

---

**It goes without saying, but the way most attorneys damage their credibility with DOJ and OIG is by not having a grasp of the facts underlying the investigation.**

---

Rest assured that when the government believes it has a strong case, it will share details to help further the case. Hopefully, this article assists how you think about and prepare for government inquiries, *qui tams*, and civil litigation. Simply having a well thought-out plan to

---

<sup>10</sup> Given the prevalence of compliance investigations in healthcare, it is critical that counsel decide in advance if they want the internal investigation material to be privileged or not. Two recent decisions make clear that courts will not hesitate to order the release of attorney-client communications if an internal investigation is not carefully initiated. In *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center*, Case No: 6:09-cv-1002, 2012 U.S. Dist. LEXIS 158944 (M.D. Fla. Nov. 6, 2012), the court ruled that hundreds of documents created by or directed to in-house counsel and compliance were not protected. The court determined that while communications with outside counsel enjoy a presumption of protection, communications between in-house counsel and corporate employees do not, and the organization has the burden of establishing that each communication is privileged. Perhaps more disturbing, in *United States ex rel. Barko v. Halliburton Co.*, 2014 U.S. Dist. LEXIS 30866 (D.D.C. Mar. 11, 2014), the court compelled production of internal investigation materials. This case highlights the risk associated with having in-house personnel involved with internal investigations. Before counsel starts to make inquiries into the underlying facts, they should carefully consider why and how to achieve their goals. If counsel intends to have privileged communications, then it should be stated explicitly that the communication is privileged and that counsel has been asked for and is providing legal advice.

address government inquiries goes a long way to ameliorating the costs of an investigation.

## II. Investigatory Process

When issues arise, companies and their counsel need to have a basic understanding of how to respond and communicate with agents and prosecutors. Fraud investigations typically start with a *qui tam* or when sources make allegations to a contractor, agency, or prosecutor. While sources are usually former employee whistleblowers, they can also be competitors or cooperators from a criminal case. Since 2007, some investigations have also started with the mining of billing data.

DOJ and OIG are not the only agencies that investigate health-care fraud. Other agencies include state Medicaid Fraud Control Units (MCFUs), Internal Revenue Service (IRS), Postal Inspection Service, Department of Defense (DOD), state insurance departments (DOI), and the Federal Bureau of Investigation (FBI).

In most cases, the first sign of an investigation is a former or current employee reporting that an agent tried to conduct an interview. These initial contacts are usually followed by subpoenas. Less often, a search warrant is executed to obtain information.

When the initiating contact is informal, corporate counsel must decide whether the situation merits involving outside counsel or further information gathering. Once the government initiates formal contact, outside counsel should be retained to represent the company.

Whatever the initial contact—letter, subpoena, or employee interview—corporate in-house counsel should focus on understanding the process and how to address the situation. Always remember that the response can set the tone for what may turn into a lengthy investigation. Given that agents are proceeding with limited, and biased, information in the initial stages, do not be surprised if government agents and attorneys seem heavy-handed.

As the investigation progresses, the government should be striving to understand the facts and not simply support some plaintiff's attorneys theories of the case. When the government is open and willing to communicate, companies can make headway by guiding investigators through documents and witnesses.

The following sections address the different types of initial contacts and provide pragmatic suggestions. Once again, every investigation is different, and the following suggestions are simply basic propositions that tend to hold true across matters.

## III. Agent Interviews & Initial Contacts

In the majority of cases, the first warning that an investigation is underway is when a former employee reports having been interviewed by FBI, OIG, or MFCU agents. After gathering as much information about that former employee and his role at the company as possible, counsel should decide whether it makes sense to have an attorney or compliance person call to get a full explanation of the questions and answers from the interview. Assuming the person is willing to talk and the subject matter is appropriate, counsel should gather as much information as possible and begin to identify issues.



If the company is the target of the investigation, the next step for counsel is to identify other individuals with knowledge. If current employees, these people can be immediately interviewed and advised on how to interact if approached by a government agent. Counsel must be mindful that the law says that a witness is not the property of the government nor the company, and that both sides should have equal access to the witness.<sup>11</sup>

Unfortunately, the legal requirements have no practical meaning if employees are unaware of their rights when confronted by investigators. When relevant individuals are identified, counsel should advise them of their legal rights and obligations should they be contacted for an interview.

Current employees should be informed that they are free to give an interview to a government agent if they choose, but if they go forward with an interview, the company expects and requires that all answers will be truthful. Also, companies may explain the benefits of preparing for an interview and how using counsel to assist in an interview may help them be better witnesses.

Among the benefits of declining to be interviewed, an individual who meets with counsel in advance will better understand the agent's methods and objectives. All employees should be advised that if they are approached by an agent, they should get a copy of the agent's card or write down the agent's information, including name, agency and phone number. Shockingly, employees often report not knowing who spoke to them.

Employees also may elect to be represented by counsel during the interview. For individuals who request to have an attorney present, the company needs to determine whether the person needs an independent attorney and whether the cost of such representation would be indemnified. These determinations need to be made by counsel after reviewing the company's governing documents.

Further, company counsel must always keep in mind the ethical rules and not cross the line of representing an individual in a personal capacity. As such, company counsel should make clear to individuals that they represent the organization.<sup>12</sup> The manner in which employees are apprised of their rights will vary depending on the circumstances, including the number of employees involved, their positions and locations, and the likelihood that the government may contact them before they can be interviewed by company counsel.

To cultivate credibility, requests for informational interviews with key employees should be made by counsel immediately and done as confidentially as possible. Gathering the information necessary to gauge the seriousness of the situation requires lawyers who know the investigatory process, the industry, and the business. Agents who sense obstreperous conduct by company

counsel may respond by escalating the investigation, or even opening a new investigation into obstruction of justice.

## IV. Subpoenas

The second way companies learn that an investigation is underway is when a subpoena is served. Subpoenas raise a host of thorny issues, particularly for large organizations which possess countless documents and substantial volumes of electronically stored information (ESI).

Where the government is investigating allegations in good faith, it is important that counsel deal effectively with subpoena requests so that agents are not incited to make more aggressive demands, seek higher penalties, or seek judicial enforcement of requests. This does not mean that all subpoenas are created equal or are reasonably designed to further the investigation. On many occasions, subpoenas are overbroad and unduly burdensome.

Subpoenas can be administrative, civil or criminal, and they can be issued pursuant to a variety of enabling statutes.

For example, typical health-care investigations usually involve Inspector General subpoenas, HIPAA subpoenas, grand jury subpoenas, or civil investigative demands (CIDs). The type of subpoena and how it is served provides a great deal of information about the nature of the investigation. Any subpoena that signals that the company is under investigation should be handled by outside counsel.

### A. Inspector General Subpoenas

OIG is authorized to conduct health-care fraud investigations related to federal payers. While the Inspector General Act (IGA), 5 U.S.C. App. 3, envisioned an independent authority with the ability to guide policy and protect federal funds from abuse, OIG has become an investigatory arm of DOJ in advancing *qui tam* cases. OIG has authority to issue administrative subpoenas pursuant to 5 U.S.C. app. 3 § 6(a)(4). The IGA authorizes subpoena *duces tecum*, or documentary requests, and subpoena enforcement proceedings are handled by DOJ.<sup>13</sup>

While the IGA does not specify sanctions for failure to comply, courts consistently enforce IG subpoenas where (a) they are issued within the statutory authority of the agency, (b) the material sought is reasonably relevant, and (c) the requests are not unreasonably broad or unduly burdensome.

In today's health-care enforcement environment, receiving an IG subpoena is a clear sign that a company has been sued in a sealed *qui tam*. After reviewing the subpoena and contacting the agent listed in the cover correspondence, OIG typically directs company counsel to call an attorney in DOJ's civil fraud section or the U.S. Attorney's office. Prior to meeting with DOJ to discuss the scope of the subpoena, counsel should attempt to understand the scope of the requests and how the company retains potentially responsive material.

Like every other kind of subpoena, hold notices should be provided to relevant personnel to assure that responsive material is not destroyed or lost prior to col-

<sup>11</sup> See *United States v. Medine*, 992 F.2d 573, 579 (6th Cir. 1993); *United States v. Matlock*, 491 F.2d 504 (6th Cir. 1974); *Gregory v. United States*, 369 F.2d 185, 188 (D.C. Cir. 1966).

<sup>12</sup> This is a key part of the "Upjohn warning" that takes its name from the *Upjohn Co. v. United States* decision in which the Court held that communications between company counsel and employees of the company are privileged, but the privilege is owned by the company and not the employee. The purpose of the warning is to remove any doubt that the lawyer speaking to the employee represents the company, and not the employee. *Upjohn Co. v. United States*, 449 U.S. 383 (1981).

<sup>13</sup> See 28 U.S.C. §§ 516-19.

lection. If the language in the subpoena is clear and easily understandable, the subpoena requests can be used in the hold. If not, counsel should craft the hold in simple and broad terms to assure employees understand what is required of them. Finally, material produced pursuant to an IG subpoena can be shared widely across government agencies.

## B. HIPAA Subpoenas

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorized DOJ to issue subpoenas for documents and testimony in investigations relating to “any act or activity involving a federal health-care offense.”<sup>14</sup> HIPAA subpoenas are sometimes referred to as Authorized Investigative Demands (AIDs).<sup>15</sup> U.S. Attorneys’ offices can issue HIPAA subpoenas directly. Since they are not issued by OIG, these subpoenas can be issued quickly by DOJ attorneys without involving OIG or FBI.

---

**There is no quicker way to get in hot water with DOJ than to do something that the prosecutors view as hurting their criminal investigation.**

---

Unlike grand jury subpoenas, the information obtained through these subpoenas allows sharing between all the attorneys at DOJ without regard to Rule 6(e).<sup>16</sup> Documents and testimony obtained through grand jury subpoenas cannot be shared absent a court order. DOJ asserts that these subpoenas better enable parallel criminal and civil proceedings.<sup>17</sup>

Unlike an IG subpoena, the receipt of an AID directly from a criminal Assistant U.S. Attorney signals an ongoing criminal investigation. The very existence of a corporate criminal investigation should heighten the level of responsiveness and internal inquiry. Further, experienced counsel is required to ensure that company activities do not interfere with the criminal prosecutors’ investigation.

There is no quicker way to get in hot water with DOJ than to do something that the prosecutors view as hurting their criminal investigation. For example, something as simple as sending a hold notice after the receipt of the subpoena without talking to the prosecutor could alert target employees to the existence of an investigation at a time when the prosecutors are conducting active undercover activities. This is why it is vital to obtain expert advice from counsel who are keenly aware of how DOJ operates.

Lastly, when a criminal investigation is underway, the company will want to know the underlying facts as quickly as possible but, again, faces the prospect of taking actions that could hurt an ongoing investigation.

<sup>14</sup> Pub. L. No. 104-191, § 248, 110 Stat. 1936, 2018 (codified at 18 U.S.C. § 3486 (2000)). See 18 U.S.C. § 3486.

<sup>15</sup> 18 U.S.C. § 3486(a)(1)(A)(i)(I).

<sup>16</sup> “Report to Congress on the Use of Administrative Subpoena Authorities by Executive Branch Agencies and Entities,” at 31, available at [http://www.justice.gov/archive/olp/rpt\\_to\\_congress.htm](http://www.justice.gov/archive/olp/rpt_to_congress.htm).

<sup>17</sup> *Id.*

## C. Grand Jury Subpoenas

Much like a HIPAA subpoena, a grand jury subpoena is used by criminal prosecutors to obtain documents and compel testimony. Whereas a HIPAA subpoena could be used in a civil matter, a grand jury subpoena cannot. Rule 6(e) makes it a criminal offense for the prosecutor to share material with civil DOJ personnel absent a court order.

A grand jury subpoena reflects that there is an open criminal investigation and that a federal prosecutor has been assigned to the matter. In addition, a grand jury subpoena for documents may be accompanied by a target letter. Most districts encourage prosecutors to advise individuals and entities of their status as a target.<sup>18</sup>

## D. Civil Investigative Demands

Since 2009, the use of CIDs has increased dramatically. CIDs are typically used when the government is investigating *qui tam* allegations. DOJ civil attorneys can use CIDs to obtain both documents and sworn testimony. Unlike traditional Rule 26 civil discovery, CIDs are employed by the government before litigation has commenced. This fact alone makes it difficult to seek judicial review or to attempt to set appropriate limits.

Prior to the Fraud Enforcement and Recovery Act (“FERA”) in 2009, only the Attorney General could authorize issuance of a CID. Therefore, CIDs were rarely used. FERA provided that the Attorney General could delegate the power to issue CIDs to U.S. Attorneys and the Assistant Attorney General for the Civil Division.<sup>19</sup> As a result, CIDs are issued with some frequency to compel sworn testimony.<sup>20</sup>

DOJ may issue a CID if there is any “reason to believe that any person may be in possession, custody, or control of documentary material or information relevant to a false claims law investigation.”<sup>21</sup> While a subpoena can only call for production of documents, CIDs can require a company to: (1) produce documents with a sworn certificate; (2) answer interrogatories; or (3) give testimony.<sup>22</sup>

The government may share any information obtained through a CID with the *qui tam* relator, so long as the government “determine[s] it is necessary as part of any false claims act investigation.”<sup>23</sup>

## V. Subpoena Response

Responding to a subpoena sets the tone for the investigation. The government expects a quick and knowledgeable response. While the topics and subpoena are new to the company, the government may have spent years investigating prior to issuing a subpoena.

<sup>18</sup> *United States Attorney’s Manual* § 9-11.15, available at [http://www.justice.gov/usao/eousa/foia\\_reading\\_room/usam/title9/11mcrn.htm#9-11.153](http://www.justice.gov/usao/eousa/foia_reading_room/usam/title9/11mcrn.htm#9-11.153).

<sup>19</sup> See Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1616, 1622 (2009).

<sup>20</sup> 31 U.S.C. § 3733(a)(1); Ty Howard, *Litigation: Examining the False Claims Act and civil investigative demands*, Inside Counsel (Sept. 5, 2013), available at <http://www.insidecounsel.com/2013/09/05/litigation-examining-the-false-claims-act-and-civi>.

<sup>21</sup> 31 U.S.C. § 3733(a)(1).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

In-house counsel needs to take three immediate steps: (1) review the request, (2) select who will interact with government, and (3) issue a hold notice. In addition, counsel at publicly traded companies need to consult with their securities counsel to ascertain if public disclosure is required.

The hold notice should be in layman's terms, include a list of documents to be retained, and instructions on how the documents will be collected. Given all the ways that information is created, stored, and deleted, the ability to satisfy investigators that non-privileged, responsive documents and communications are being retained, reviewed and produced is an important aspect of successfully responding to and defending against governmental action.

As soon as the company assesses the state of its records and its ability to comply, counsel should meet with the government to narrow the request to the simplest universe of material that will satisfy the government. Common topics of discussion include time periods, clarity and breadth of requests, response times, ESI issues, and privilege.

Counsel should always convey a commitment to promptly handle the subpoena. Counsel who can persuade the government that the company is dedicated to addressing the underlying issues in an investigation will be more successful in winning concessions on subpoenas.

## VI. Search Warrants

In health-care investigations, search warrants are rarely used except in the most serious criminal cases. Even though rare, counsel should know the process and have a plan to deal with a warrant should one be executed.

First, employees should know to contact counsel or a designated point-person immediately when a warrant is presented. The warrant should be inspected for facial sufficiency (location, time, date and scope) and everyone should be instructed to comply with its terms.

Never obstruct agents. Instead, express your concerns, document your objections, and ask the lead agent to contact your criminal defense counsel. Thereafter, send home all nonessential employees—doing so limits the number of potential interviews and assures that employees do not expand the scope of the search by consent. Request a copy of the affidavit filed in support of the warrant. The agent will tell you that the affidavit is under seal. Do not discuss the facts with the agents during a search.

Warrants permit the government to seize original documents. To safeguard a provider's interests, counsel

should request copies of items seized and/or the return of critical documents. One person should try to keep track of the areas searched, questions asked, and items taken.

In most instances, it is generally beneficial to assist the agents in locating the items listed in the warrant to speed the process. Everyone should be professional and courteous to agents. At the end of the search, counsel should request an inventory and attempt to assure that the inventory fully describes the items seized.

One final note: federal agents are always excited to execute a warrant, but they quickly become less energized when they have hundreds of boxes of medical records and other material to handle.

## VII. Disclosure of Investigation

For public companies, disclosing facts to investors about an investigation can be a difficult decision that will have significant business and legal ramifications. Companies will want to consult with their securities counsel to make this decision. In general, securities laws impose a duty to disclose specific events that may arise during an investigation.

For example, a company must disclose when an investigation has grown to the point where there is a "material pending legal proceeding," or where such a proceeding is "known to be contemplated" by a governmental authority, or where a director of an issuer is a defendant in a pending criminal proceeding.<sup>24</sup>

## VIII. Conclusion

Knowing the process, understanding the significance of how the government is proceeding, and making sound decisions can reduce the emotional and financial expense of dealing with an investigation.

Effectively and efficiently dealing with the government does not mean assuaging the government attorneys and agents. It requires building credibility with key agents by following the law, understanding the evidence, keeping your word, acting in good faith, communicating openly and honestly, and avoiding gamesmanship.

Counsel who establish credibility will receive the benefit of the doubt in the long run and will be in the best position to fully resolve the issues.

<sup>24</sup> See 17 C.F.R. § 229.103 (2009) (disclosure of "legal proceedings"); *id.* at § 229.401(f) (disclosure concerning involvement of directors or executive officers in certain legal proceedings). But even where specific disclosure requirements are set forth as in United States Securities and Exchange Commission ("SEC") Form 8-K or Regulation S-K, those requirements are subject to interpretation.