

The Most Challenging Compliance Arena in Health Care: Pharmaceutical and Medical Device Manufacturing



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Compliance Professionals Can Take Steps to Better Prepare Themselves and Their Companies to Deal with Allegations of Wrongdoing

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PHARMACEUTICAL AND MEDICAL DEVICE ENFORCEMENT OVERVIEW

Through the use of the civil False Claims Act (FCA), the U.S. Department of Justice (DOJ) has settled cases netting \$30 billion over the last 10 years.¹ This \$30 billion represents nearly 50 percent of all FCA recoveries since the law's enactment in 1863, and the majority of this sum is the result of *qui tam* cases initiated by whistleblowers against health care companies.² While FCA settlements touch all sectors within health care, pharmaceutical and medical device manufacturers make up a disproportionate share of the companies targeted by whistleblowers and DOJ.³

Over that same 10-year period, manufacturers have made revolutionary advances in both drugs and devices that have improved the quality and length of life for millions. Yet, manufacturers continue to face expanding internal or governmental investigations. There is no doubt that the profitability of manufacturers creates an opportunity for whistleblowers to advance personal financial interests, but with increased profits should come the increase in the concomitant obligation to assure the highest levels of compliance. For these manufacturers, compliance professionals serve to protect the interests of shareholders, management, governmental programs, and the patients the companies serve. Simply put, the cost of non-compliance includes the substantial risk of repayment and penalties, the expenses of counsel, consultants, monitors, as well as the impact on employee morale and company reputation. Furthermore, excellence in compliance serves to protect companies and

management from the threat of criminal enforcement.

After outlining specific risks faced by manufacturers, this article addresses the governmental investigation process and how compliance professionals may better prepare themselves and their companies to deal with allegations of wrongdoing. The one rule for handling allegations that rise to the level of interacting with government enforcement officials is simply maintain credibility with the government. This means that the individuals dealing with the government on behalf of the company have integrity and are known throughout the institutions for their honesty. Each one of these traits is especially important when complex regulatory and litigation issues require aggressive advocacy.

The United States spends roughly one-fifth of its gross domestic product (GDP) on providing health care.⁴ Given the breadth of governmental spending, it is concerning that so much of DOJ's enforcement focus has been placed on manufacturers, a narrow segment of companies within our system. Key factors in DOJ's interest in manufacturers include the level of competition for market share, direct marketing to prescribers, and perceived profitability. Recent studies have reported that manufacturers spent over \$24 billion on marketing directly to prescribers in 2012,⁵ and a recently published study found that hospitals that restricted manufacturer sales representatives' ability to market to physicians led to a statistically significant increase in the use of more cost-effective generic drugs.⁶ In short, the amount of money used by the industry to gain market share and drive sales, and the impact those efforts have on prescribers, creates a ready environment for whistleblowers and DOJ to dig deep into manufacturer conduct. Finally, it should not go without comment that manufacturers spend billions on the research and development of new and improved life-saving products that require substantial

efforts to educate physicians regarding the benefits.

For manufacturers, recent investigations and cases have centered on particular issues that compliance officers would be wise to explore. Those areas of concern include, but are not limited to, the following: (i) patient assistance programs (PAPs) and related patient access services, including product adherence or reminder/refill initiatives; (ii) reimbursement support services; (iii) interactions, arrangements, and communications with specialty pharmacies; (iv) speaker programs; (v) consulting arrangements, including advisory boards; (vi) product pricing, including price reporting, discounts, and rebates; (vii) field medical activities, including interactions with managed care customers and payers (pharmacoeconomic presentations), as well as interactions with internal commercial personnel, and (viii) interactions with non-traditional health care stakeholders, such as Clinical Practice Guideline (CPG) committees, compendia, clinical pathways, group purchasing organizations (GPOs), and patient or disease advocacy groups. Before addressing recent cases and public investigations, we set forth the legal framework that should be familiar to compliance officers.

LEGAL ENFORCEMENT FRAMEWORK

Compliance professionals within manufacturers should have a thorough understanding of the FCA, anti-kickback statute (AKS), and the Federal Food, Drug, and Cosmetic Act (FDCA). While this article is not intended to provide a full overview of the law, we provide a high-level overview as a starting point for the discussion of key cases and investigations.

The FCA provides that any person who knowingly⁷ submits or causes the submission of a false claim⁸ to the government is liable for three times the amount of the damage sustained plus mandatory penalties.⁹ It imposes liability on any person who knowingly makes or uses, or causes to be

made or used, false records or statements material¹⁰ to an obligation¹¹ to pay money or property to the government, or knowingly concealing or improperly avoiding or decreasing an obligation to pay money to the government.¹² How the FCA applies in a given case depends on the theory of liability being asserted by the enforcers. FCA allegations may be premised on “factually false” or “legally false” claims.¹³ “Legally false” allegations include theories based on express or implied false certifications.

The AKS prohibits any person from knowingly and willfully paying remuneration to any person with the intent to induce that person to purchase, prescribe, recommend, or refer a person for the furnishing of items or services payable under a federal health care program.¹⁴ DOJ routinely refers to the AKS as a law that covers any arrangement in which one purpose, often referred to as a “single purpose,” of the remuneration was to induce prescriptions.¹⁵ While a criminal statute, alleged violations of the AKS are most commonly made in the context of FCA investigations and cases.¹⁶ To make matters more complicated, conduct that falls within a safe harbor or statutory exception may not be considered a violation of the AKS.¹⁷ Allegations of AKS violations are extremely serious and difficult to handle for manufacturers. Even in the absence of any evidence of wrongful intent, the chances of persuading an investigator that a purpose of giving something of value to a prescriber did not involve a desire to increase sales borders on impossible.

For arrangements outside of a safe harbor that “implicate” the AKS, enforcers seek to ascertain whether the practice creates a risk to federal health care programs or their beneficiaries. In assessing potential risks, enforcers are most concerned with arrangements that (i) interfere with clinical decision-making, (ii) increase costs to federal health care programs; (iii) increase the risk of overutilization or inappropriate utilization; (iv) raise patient safety or quality of care concerns;¹⁸ (v) entail “white

coat” marketing (where financial interests or biases are not clearly transparent);¹⁹ and (vi) acts that result in unfair competition.²⁰ These factors are often referred to as the “prudential factors” because they correspond with the underlying purpose of the AKS — to avoid corrupting the doctor-patient relationship.

Unlike other participants in the health care system, manufacturers also must comply with the FDCA and its regulations. Unlike the FCA and AKS, the FDCA contains an abundance of strict liability provisions that prohibit manufacturers from introducing, delivering, or causing to be introduced into interstate commerce a misbranded or adulterated drug,²¹ which includes, among other things, a “new drug”²² or an unapproved drug, including an unapproved use or indication of an approved drug. The FDCA prohibits labeling or advertising that is false or misleading and that causes a drug to be “misbranded.”²³ DOJ may seek to impose criminal and civil penalties for FDCA violations.

RECENT ENFORCEMENT CASES AND INVESTIGATIONS

Reimbursement Support Services

Over the last several years, DOJ has taken a keen interest in certain “value added” services provided by manufacturers to referral sources. Given payer restrictions on coverage and the complexities of coding for new products, manufacturers regularly provide and their customers demand reimbursement support services. In 2003, the Office of Inspector General’s (OIG’s) Compliance Program Guidance for Drug Manufacturers explained that a manufacturer’s provision of “limited reimbursement support services in connection with its own products” has “no independent value.” Notwithstanding the guidance, a number of recent *qui tam* complaints have asserted that reimbursement support services violated AKS and FCA. The cases tend to focus on situations where the government believes that the

support services: (i) are comprehensive, instead of limited, thus having independent financial value; (ii) involve skewed or false clinical information being presented to payers by non-clinically trained commercial personnel; (iii) are likely to cause the submission of claims for off-label or unapproved uses; and (iv) mislead payers regarding the identity of the organization providing the support. Allegations have been brought, and some cases settled, involving ISTA,²⁴ Shire,²⁵ Warner Chilcott,²⁶ Respironics,²⁷ Cephalon,²⁸ Allergan, and Biogen Idec.

Speaker Programs and Consultants

DOJ continues to aggressively pursue allegations of improper payments in the form of speaker payments, speaker training, honoraria, and associated expenses. Recent cases have involved Biogen Idec,²⁹ Forest Labs,³⁰ Cephalon,³¹ Pfizer,³² and Teva.³³ Allegations that have interested DOJ included: (i) payments to physicians who were selected on their volume rather than clinical knowledge, expertise, or reputation, (ii) payments to physicians to speak on duplicative topics, and (iii) payments to physicians to speak to their own staff, and payments for excessively expensive meals.

Off-Label Promotion

While manufacturers may now be more comfortable that truthful, non-misleading representations should not lead to enforcement activity, it remains an arena in which investigations are focused on the mechanics, reliability, and veracity of promotional activities. In *Sorrell v. IMS Health, Inc.*, the Supreme Court held that content-based or speaker-based restrictions on commercial speech are subject to “heightened judicial scrutiny.” The Court observed that “[s]peech in aid of pharmaceutical marketing... is a form of expression protected by the Free Speech Clause of the First Amendment.”³⁴

Shortly after *Sorrell*, courts began applying this precedent in the context of FDA’s

regulations governing manufacturers’ speech. In *United States v. Caronia*, for example, the Second Circuit applied *Sorrell*’s heightened scrutiny test to hold that the FDCA and FDA’s implementing regulations could not be interpreted to permit a misbranding conviction based on truthful and non-misleading speech alone, even if the speech was off-label.³⁵ The Second Circuit explained that prohibiting truthful off-label speech by manufacturers fails even the intermediate scrutiny standard under *Central Hudson*.³⁶ Because off-label prescribing is not illegal, the court found that a complete ban on speech about off-label use simply does not advance a legitimate government interest.³⁷

There have been two chief types of claims lodged against manufacturers: (i) false and misleading statements to payers, managed care customers and similar entities (*e.g.*, withholding safety information, not providing adequate risk information, misstating facts, unsubstantiated superiority claims, et cetera) in order to achieve favorable placement on a payer’s formulary; and (ii) providing unlawful remuneration to payers, managed care customers, formulary committees (including individual members), and other individuals with influence into formulary decisions in return for favorable placement on a payer’s formulary. Other cases have focused on manufacturer interactions and relationships with certain types of health care stakeholders that may influence prescribing decisions or make recommendations regarding clinical treatment. Specifically, several cases have included allegations that manufacturers have made improper or unlawful payments to influence: (i) quality measure organizations; (ii) CPG entities; and (iii) clinical pathway or treatment algorithm entities, as well as individual members of these entities.

Specialty Pharmacies

DOJ has been pursuing alleged improper payments to specialty pharmacies for several years. When a manufacturer’s conduct

is alleged to direct prescriptions to pharmacies based on refill and adherence rates, enforcers are likely to investigate the conduct. In addition, payments that may take the form of rebates and discounts to certain pharmacies may draw added attention.

PILOTING GOVERNMENTAL INVESTIGATIONS

Regardless of the origin of the investigation, compliance personnel must be prepared to effectively and efficiently address issues as they arise. Given the enforcement environment for manufacturers, nothing is more important than understanding how to present and promote integrity and credibility during an investigation. In the FCA context, manufacturers often find themselves in the unenviable position of having to establish innocence to enforcers as opposed to defending against unfounded allegations.

This section provides an overview of the investigatory process and puts forward a few suggestions for compliance and counsel to consider when dealing with an external investigation. Once again, the key point is that every manufacturer needs to establish and keep credibility with the government attorneys and agents who control and guide the investigation. Building credibility with the government does not mean appeasement, but it requires adherence to the law, good faith, open communications, and candor.

Counsel and compliance personnel who lose credibility with the government draw added scrutiny, whereas those who establish it will receive the benefit of the doubt. This is especially true in the long run, but it is also important during initial encounters when enforcers have a one-sided, truncated view of the facts. The most frequent effort by compliance and counsel — and the way the most damage is done to the manufacturer's credibility — is by failing to understand the facts. Any failure to fully understand the details of what happened and how it happened risks being perceived as an effort to mislead enforcers.

The first step when a potential issue arises is to preserve, gather, and understand the facts.³⁸ It is worth noting that every investigation is unique and there is no single process for success. There are, however, basic principles that can help manufacturers build credibility while addressing subpoenas, interview requests, and civil investigative demands.

Investigatory Process

When issues with the government arise, most manufacturers have had previous experience and understand the importance of initial contacts and representations. The first sign of an investigation is typically the service of a subpoena, although in some more serious matters it may come to an employee's attention that a former employee has been approached by law enforcement. Whatever the initial contact, the manufacturer should focus on understanding the process and how to deal with the enforcers. The initial response can set the tone for what may turn into a lengthy investigation.

Finally, if the manufacturer is aware of the issues being investigated based on prior compliance work and suspects a whistleblower may have filed an FCA case, it is worth noting that the enforcers probably are well aware of that internal process. While tempting to attack a disingenuous whistleblower, it does little to advance the manufacturer's position in the eyes of the government.

Given that enforcers are proceeding with limited information in the initial stages that is skewed by a whistleblower, it should not be surprising if the government seems heavy-handed. As the investigation progresses, the government should be striving to understand the facts and not simply extort a settlement based on the costs associated with the investigation. When the government is open and willing to communicate, manufacturers can make headway by guiding investigators through documents and witnesses. Once again,

every investigation is different, and these suggestions are simply basic propositions that tend to hold true across matters.

Interviews and Initial Contacts

In most investigations, law enforcement officials will want to interview individuals. When a former employee has been interviewed without advance notice, those representing the manufacturer need to acquire as much information as possible about that former employee and his role at the company, what was asked of that person, and what was relayed. If any misstatements were made, it is important to encourage the witness to correct the statement. When a request is made in advance to interview a current employee, counsel and compliance have more work to do to assure that the interview is done appropriately. Assuming the individual is willing to give an interview and the subject matter is appropriate, counsel should prepare the witness to truthfully and completely answer the questions that are asked of him.

To prepare for interviews, counsel will need to explore the legal issues with all relevant documents and other knowledgeable individuals in order to understand how best to prepare witnesses. In most situations, counsel can interview current employees with key documents in short order. Employee witnesses are not the property of the government or the manufacturer,³⁹ so counsel must be careful in explaining rights and responsibilities to individuals.

All 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, all answers must be truthful. Also, manufacturers should explain to employees the benefits of preparing for an interview with the government and how using counsel to assist in an interview may help. Further, employees should be advised that if they are approached by an agent, they should request and retain the agent's personal

information, including name, agency, and phone number.

Counsel for the manufacturer should make clear to every individual interviewed that they represent the organization.⁴⁰ While the manner in which employees are apprised of their rights may 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, it is worth assuring that employees understand some basic ground rules and how frequently the government conducts investigations.

To cultivate credibility both inside and outside the organization, requests for informational interviews with key employees should be made quickly and done as confidentially as possible. Gathering the information necessary to gauge the seriousness of the situation requires counsel and compliance experts who know the investigatory process, the manufacturer, its products, and market competition. Agents who sense obstreperous conduct by counsel or compliance will respond by escalating the investigation.

Subpoenas

Subpoenas to manufacturers raise a host of prickly issues, particularly for large organizations which possess millions of pages of documents and substantial electronically stored information (ESI). When the government is investigating allegations in good faith, subpoenas are used in an effort to assure that materials are preserved and critical materials — those that would allow the enforcers to make decisions — are produced. 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, but most government agents and attorneys are willing to be reasonable in narrowing the scope of review.

Subpoenas can be administrative, civil, or criminal, and they can be issued pursuant to a variety of enabling statutes. For example, investigations of manufacturers usually involve Inspector General Subpoenas, Health Insurance Portability and Accountability Act of 1996 (HIPAA) subpoenas, grand jury subpoenas, or civil investigative demands (CIDs). The type of subpoena and how it is served provides some information about the nature and scope of the investigation.

OIG is authorized to conduct health care fraud investigations related to federal payers. While the Inspector General Act envisioned an independent authority, OIG typically acts as part of an investigatory team with DOJ advancing *qui tam* cases. OIG has authority to issue administrative subpoenas pursuant to 5 U.S.C. app. 3 §6(a)(4). These are documentary requests, and subpoena enforcement proceedings are handled by DOJ.⁴¹ While the authorizing statute does not specify sanctions for failure to comply, courts consistently enforce Inspector General (IG) subpoenas where (i) they are issued within the statutory authority of the agency, (ii) the material sought is reasonably relevant, and (iii) the requests are not unreasonably broad or unduly burdensome. In most cases, receipt of an IG subpoena is a signal that a company has been sued in a sealed *qui tam*. IG subpoenas are typically handled by attorneys in the civil section of the U.S. Attorney's office or main justice. Documents produced pursuant to an IG subpoena can be shared widely across government agencies.

HIPAA authorized DOJ to issue subpoenas for documents and testimony in investigations relating to "any act or activity involving a federal healthcare offense."⁴² HIPAA subpoenas are sometimes referred to as Authorized Investigative Demands (AIDs).⁴³ U.S. Attorneys' offices may issue HIPAA subpoenas directly without involving agents. Documents and testimony obtained through these subpoenas may be

shared widely between agencies, and DOJ claims that these subpoenas better enable parallel criminal and civil proceedings. Unlike an IG subpoena, the receipt of an AID directly from a criminal Assistant U.S. Attorney signals that there may be an ongoing criminal investigation. Obviously, the existence of a corporate criminal investigation should heighten the level of concern.

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.⁴⁴

Since 2009, the use of Civil Investigatory Demands (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 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. FERA allowed the Attorney General to delegate the power to issue CIDs to U.S. Attorneys and the AAG for the Civil Division.⁴⁵ As a result, CIDs now are issued with frequency to compel sworn testimony.⁴⁶ 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.”⁴⁷ 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. 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.”

Responding to Subpoenas

Prior to interacting with DOJ to discuss the subpoena, counsel should attempt to understand the scope of the requests and how the manufacturer retains responsive material. For every kind of subpoena, hold notices should be provided to relevant personnel to assure that responsive material is not destroyed or lost prior to collection. If the language in the subpoena is clear and easily understandable, the subpoena request language 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.

Responding to subpoenas sets the tone for the investigation in most matters. The government expects a quick and knowledgeable response. While the topics and subpoena are new to the company, the government may have spent months investigating prior to issuing a subpoena. Counsel needs to take three immediate steps: (i) review the requests, (ii) select who will interact with government, and (iii) issue a hold notice after discussing the hold with the government attorney. In addition, counsel at publicly traded companies need to consult with their securities counsel to ascertain if public disclosure is required. Given all the ways that information is created, stored, and deleted, the ability to satisfy enforcers that 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 seek to narrow the request to the simplest universe of relevant material. Common topics of discussion include time periods, custodians, refining broad requests, response times, electronically stored information (ESI) issues, and privilege.

Disclosure of Investigation

For public companies, disclosing an investigation can be a complicated 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 is a defendant in a pending criminal proceeding.⁴⁸

CONCLUSION

After years of an intense focus on pharmaceutical and medical device manufacturers, ongoing investigations appear to indicate that the government will continue to focus on these sectors in the health care market. Knowing the process, understanding how the government is proceeding, and making sound decisions can reduce the expense of handling an investigation. It requires building credibility with the government by understanding the evidence, keeping your word, acting in good faith, communicating openly, and avoiding gamesmanship.

Endnotes:

1. False Claims Act, ch. 67, 12 Stat. 696 (1863)(codified as amended at 31 U.S.C. §§ 232-235). The 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.* “[A]pproximately \$29.4 billion [has been] returned by the HCFAC account to the Medicare Trust Funds since the inception of the Program in 1997.” 2015 HCFAC Report at 1.
2. *Id.* By most accountings, health care companies account for approximately two-thirds of the \$30 billion. DOJ claims it has received over \$26 billion in payments from settling FCA actions since 2009. Dept. of Justice, Press Release, Justice Department Recovers Over \$3.5 Billion From False Claims Act Cases in Fiscal Year 2015 (Dec. 3, 2015), available at www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.
 3. Press Release, Dept. of Justice, Justice Department Celebrates 25th Anniversary of False Claims Act Amendments of 1986 (Jan. 31, 2012), available at 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 Corporation (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)”).
 4. “U.S. health care spending grew 5.8 percent in 2015, reaching \$3.2 trillion or \$9,990 per person. As a share of the nation’s GDP, health spending accounted for 17.8 percent.” See CMS, *The National Health Expenditure Accounts (NHEA) Report*, Dec. 6, 2016 www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical.html.
 5. See CegeDim Strategic Data, 2012 U.S. Pharmaceutical Company Promotion Spending (2013), www.skainfo.com/health_care_market_reports/2012_promotional_spending.pdf.
 6. See Larkin, Ang, Steinhart, et. al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, JAMA, 317(17):1785-1795 (May 2, 2017).
 7. Defined as (1) actual knowledge that the claim or statement was false; (2) deliberate ignorance of truth or falsity of the claim or statement; or (3) reckless disregard of the truth or falsity of the claim or statement. 31 U.S.C. § 3729. However, the government is not required to prove specific intent to defraud.
 8. Defined as “any request or demand . . . for money or property” that: “(i) is presented to an officer, employee, or agent of the United States,” or “(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government . . . provides or has provided any portion of the money or property requested or demanded.”
 9. The Bipartisan Budget Act of 2015 contains a section entitled the “Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015” that requires federal agencies to update the level of their civil monetary penalties to account for inflation. See H.R. 1314, 114th Cong. § 701 (as passed by the House and Senate, Oct. 30, 2015) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note). As agencies adjust their penalty provisions, defendants might see penalties that exceed \$21,000 per claim. Notably, most settled FCA cases do not involve the payment of penalties. See also 31 U.S.C. § 3729(a); see also 28 C.F.R. § 85.3.
 10. Defined as “having a tendency to influence or be capable of influencing payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).
 11. Defined as “an established duty, whether or not fixed, arising from an express or implied contractual . . . relationship, from statute or regulation, or from the retention of any overpayment.” *Id.* at § 3729(b)(3).
 12. *Id.* at § 3729(a)(1)(6).
 13. See *Conner*, 543 F.3d at 1217 (citing *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)).
 14. See 42 U.S.C. § 1320a-7b(b).
 15. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985); see also *United States ex rel. Nevyas v. Allergan*, no. 2:09-cv-00432 (E.D. Pa.), n.1, ¶15 (citing *Greber*, 760 F.2d at 69).
 16. 42 U.S.C. § 1320a-7b(g).
 17. The most commonly used safe harbors or statutory exceptions for manufacturers in their interactions with health care professionals are: (1) the personal services safe harbor; (2) the discount safe harbor; and (3) space or equipment rental safe harbor. While the OIG has asserted that safe harbor protection requires exacting compliance with all of the requirements, it has also noted that noncompliance with a safe harbor does not make an arrangement illegal *per se* because, as an intent based statute, each arrangement must be evaluated on a case-by-case basis to assess the intent of the parties.
 18. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734 (May 5, 2003).
 19. OIG A.O. 02-12 (Aug. 30, 2002).
 20. OIG A.O. 12-19 (Dec. 7, 2012).
 21. 21 U.S.C. § 331(a).
 22. A “new drug” is defined as one whose composition has not been recognized by qualified experts as safe and effective for the intended use. 21 U.S.C. § 321(p).
 23. 21 U.S.C. § 352(f).
 24. *United States ex rel. DJ Partnership v. ISTA*, No. 1:11-cv-00367 (W.D.N.Y.) Complaint at ¶¶ 271–83.
 25. See also *United States ex rel. Harris et al. v. Shire PLC*, No. 1:09-cv-06994 (N.D. Ill.).

26. See *United States ex rel. Alexander et al. v. Warner Chilcott PLC, et al.*, No. 1:11-cv-10545 (D. Mass.), Third Amended Complaint (Aug. 22, 2013).
27. *U.S. ex rel. Ameer v. Respironics, Inc.* No. 2:14-cv-02077 (D.S.C.).
28. *United States ex rel. Cestra, v. Cephalon Inc., et al.*, No. 2:14-cv-01842, Memorandum at p. 3 (E.D. Pa. Jun. 3, 2015)(citing ¶¶ 219-37 of relator Cestra’s Second Amended Complaint).
29. *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 1:12-cv-10601 (D. Mass.) Second Amended Complaint.
30. *U.S. ex rel. Kroening v. Forest Pharm. et al.*, No. 2:12-cv-00366 (E.D. Wisc.), Second Amended Complaint (alleging that Forest: (i) paid kickbacks to physicians in the form of speaker fees (\$1,000 - \$1,250 per event), among other things, to induce them to prescribe Forest products--so called “Pay-to-Play” scheme; (ii) targeted high prescribers for alleged kickbacks; (iii) conducted return-on-investment (ROI) analysis on speaker fees and other payments to see whether HCPs increased prescriptions, which included tracking HCP weekly Rx data; and (iv) some speaker programs were shams, with little/no educational content, no prescribing attendees or only one attendee, often a “friend” of the speaker, and/or lavish entertainment venues not conducive to learning.
31. *United States ex rel. Cestra, v. Cephalon Inc., et al.*, No. 2:14-cv-01842 (E.D. Pa.) Third Amended Complaint; *United States ex rel. Boise et al., v. Cephalon, Inc., et al.*, No. 2:08-cv-00287 (E.D. Pa.), Third Amended Complaint.
32. *United States ex rel. Brown and Vezeau, v. Pfizer, Inc.*, No. 2:05-cv-06795 (E.D. Pa.)(alleging that Pfizer: (1) paid kickbacks to HCP in the form of speaker fees and training fees (both \$1,500 each); (2) created a “national network of 350-400” paid Vfend speakers, including over 200 KOLs by September 2001 prior to Vfend’s launch to “carry the Vfend off-label message”; (3) designated “high volume” prescribing physicians as “fellows” or “Pfizer Crusaders” and then paid for their dining and other expenses in connection with industry and Pfizer sponsored events as well as vacation schedules.
33. *United States ex rel. Arnstein et al. v. Teva Pharm. et al.*, No. 1:13-cv-03702 (S.D.N.Y.)(alleging that: (1) Teva paid physicians to serve as speakers and consultants (\$1,500 - \$2,700 for each program) in connection with sham speaker program and events in violation of the AKS; (2) physicians were only permitted to remain as speakers if they increased the number of prescriptions written for Copaxone or Azilect; (3) in 2011, Teva hosted 1,329 speaker programs, which increased to 5,036 in 2012, and roughly 4,600 in 2013. The complaint states that Teva trained approximately 420 speakers for Copaxone® and 410 for Azilect.® Relators include a list of speakers in their complaint and allege that Teva paid more than \$10 million in speaker fees in 2012 alone and more than this amount in 2013 and 2014.; (4) certain physicians spoke between 40-80 times in 2013; and (5) Teva violated the PhRMA Code, and did not complete any business needs-assessments or fair market value (FMV) analysis before paying speakers. Instead, Teva added paid speakers on the basis of return on investment (ROI) analysis, which measured which speakers were more likely to prescribe Teva’s drugs or increase their prescribing.
34. S. Ct. 2653 (2011).
35. 703 F.3d 149 (2012).
36. 447 U.S. 557 (1980).
37. *Id.* at 166-67.
38. Given the prevalence of investigations, it is critical that compliance and counsel decide in advance if they want any internal investigation to be covered by attorney-client privilege. Where issues are highly complex and involve assessments of intent that may turn on a nuanced review of material, it is wise to conduct an internal investigation under privilege that will allow for attorneys to have a good-faith, fulsome exploration of the conduct and the legal implications. 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.
39. 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).
40. The “Upjohn warning” 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). Further, after the issuance of the *Yates Memorandum*, cooperation on behalf of a manufacturer may involve relaying detailed information about an individual and their conduct to the DOJ. Department of Justice: Sally Quillian Yates, *Memorandum Re. Individual Accountability for Corporate Wrongdoing* (September 9, 2015), available at bit.ly/justice-dag (hereinafter the "Yates Memo"). In the interest of fairness to individuals, it may be worth explaining after the Upjohn warning what the Yates Memo means and how it operates.

41. See 28 U.S.C. §§ 516-19.

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

43. 18 U.S.C. § 3486(a)(1)(A)(i)(I).

44. *United States Attorney's Manual* § 9-11.15, available at <http://www.justice.gov/usao/eousa/>

foia_reading_room/usam/title9/11mcrm.htm#9-11.153.

45. See Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1616, 1622 (2009).

46. 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 www.insidecounsel.com/2013/09/05/litigation-examining-the-false-claims-act-and-civi.

47. 31 U.S.C. § 3733(a)(1).

48. 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.

