

## **Are Clinical Trial Sponsors the Next Target for False Claims Act Enforcement?**

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### **Introduction**

For nearly a decade, medical device manufacturers and pharmaceutical companies escaped the reach of the federal False Claims Act, in part because these organizations do not bill federal healthcare programs directly. However, times have changed with novel legal theories, government allegations of conspiracies, and some highly publicized settlements.

This article will review the basic elements of the False Claims Act and recent settlements that clearly demonstrate the Government's intention to use the statute against pharmaceutical companies and device manufacturers who "cause" false claims to be submitted by healthcare providers. Although none of these settlements relate to actions during clinical trials, the principles certainly apply. The types of fraudulent activities discussed in recent settlements will be related to problematic contractual provisions in clinical trial agreements and other erroneous billing guidance that study sponsors may provide to clinical investigators that could cause clinical trial sponsors to become enforcement targets.

The False Claims Act is just one of the many anti-fraud weapons at the Government's disposal and, depending on the type of fraudulent activity alleged in the case, is often used in combination with other fraud and abuse laws, such as the federal anti-kickback statute. This article will not address these other laws, although they were invoked in some of the settlements described below.

### **False Claims Act (31 U.S.C. §§ 3729-3733)**

Sometimes referred to as the "Lincoln Law," the False Claims Act (hereinafter, the "Act") was originally enacted in 1863 at President Lincoln's urging to help fight fraud perpetrated by suppliers to the Union Army. In what is called the "qui tam" provision, private citizens (aka "whistleblowers") who filed lawsuits on behalf of the government were offered a reward of 50% of the amount recovered. The Act was amended in 1943 to, among other things, reduce the qui tam plaintiff's share of the recovered proceeds to between 10% and 25%. As a result, the Act fell into disuse and was largely forgotten.

In 1986, Congress made substantial revisions to the Act that again resulted in widespread use by whistleblowers. For example, the plaintiff's share of recovered proceeds was increased and a provision requiring the party defrauding the government to pay the successful whistleblower's attorney fees was added. In some settlements, these changes may mean that the whistleblower never incurs attorney fees, making qui tam lawsuits an attractive avenue for disgruntled employees.

Approximately 70% of the record \$2.1 billion recovered under the Act in the government's fiscal year 2003 was associated with lawsuits initiated by whistleblowers. In another banner year, fiscal year 2006, whistleblower lawsuits accounted for 40% of the \$3.1 billion recovered. The majority of settlements discussed in this article were brought about by whistleblowers, whose attorneys often advanced novel legal theories.

Generally speaking, the Act holds a person or entity liable for, among other things, “knowingly submitting or causing to be submitted” false claims for payment to U.S. government officials. Violators are subject to civil monetary penalties of not less than \$5,500 and not more than \$11,000 per false claim, plus up to three times the amount of damages which the government sustains because of the false claims.

For purposes of the Act, “knowingly” does not require that a person or entity has actual knowledge that information in the false claim is untrue. The 1986 amendments made the definition of “knowingly” broad enough to include claims submitted with deliberate ignorance or in reckless disregard for the truth of the statements. In other words, no proof of specific intent to make a false claim is required.

Further, as with all civil actions, the standard of proof is lower than the “beyond a reasonable doubt” standard in criminal cases. Government lawyers or whistleblower’s attorneys can prove their cases under the Act using a “preponderance of the evidence” standard. Under this standard, the evidence presented by the attorneys can be “more likely true than not.”

### **Enforcement Examples**

The following settlements illustrate government enforcement of the Act against pharmaceutical companies and device manufacturers who “cause” false claims to be submitted by healthcare providers:

#### **LifeScan, Inc.**

One of the earliest healthcare false claims settlements involved a medical device manufacturer that allegedly “caused” false billings to federal health programs by making false statements to the Food and Drug Administration (“FDA”). In December 2000, LifeScan Inc., a subsidiary of Johnson & Johnson, paid \$60 million to settle allegations that it had “knowingly” marketed adulterated and misbranded medical devices (blood glucose monitoring systems) in violation of the Food, Drug and Cosmetic Act (“FDCA”). The two whistleblowers, former employees, identified two defects in the monitoring system that led to a number of false readings that were known to Lifescan, but not disclosed to the FDA in submissions for marketing approval. Further, after market approval, several users reported adverse events related to the defects, which should also have been submitted to FDA, but were not.

While it is not unusual for device manufacturers to be held accountable for violations of the FDCA, the LifeScan case was unusual in that the manufacturer’s actions resulted in liability for false claims as well, a theory first advanced by the whistleblowers. Approximately half of the \$60 million settlement went towards resolving allegations of violations of the Act under the theory that if the FDA had known about the problems, it would not have approved the device as it was labeled and therefore, the device would not have been reimbursed by Medicare and other federal health programs. In other words, LifeScan “caused” consumers who had purchased the faulty monitoring system to submit “false claims” to Medicare for reimbursement.

The LifeScan case appears to have opened broad new avenues of liability for pharmaceutical companies and medical device manufacturers for violations of just about any statute or regulation with a “downstream” effect on government reimbursement of healthcare items and services. For example, a line of more recent settlements advances the theory that pharmaceutical companies misrepresenting results of clinical trials and otherwise promoting off-label uses of their product, uses that have not been studied in clinical trials, can be held accountable for false claims under the Act. While it is not necessarily fraudulent for an individual physician to prescribe a drug for an off-label use and bill for it, if the off-label use

is actively marketed to physicians by the manufacturer's sales force in violation of the FDCA or FDA regulations, allegations of false claims come into play. Again, the theory is that federal and state healthcare programs would not have reimbursed for the drug knowing it was being prescribed for a use not approved by the FDA as a result of an illegal off-label marketing campaign.

### **Warner-Lambert**

In another early settlement, Warner-Lambert agreed to pay \$430 million in May 2004 to resolve criminal and civil liabilities in connection with its Parke-Davis division's illegal and fraudulent promotion of its drug, Neurontin. The portion of the settlement directly applicable to allegations of violations of the Act was approximately \$152 million.

The FDA approved Neurontin in December 1993 solely for use as an adjunctive or supplemental anti-seizure medication for epilepsy. However, according to the Department of Justice ("DOJ") press release announcing the settlement, "...from mid-1995 to at least 2001, the growth of off-label sales was tremendous." <sup>1</sup> Warner-Lambert's written marketing plans and other evidence demonstrated that it aggressively marketed Neurontin to treat a wide array of non-epileptic disorders, including bipolar disease, as well as first-line monotherapy treatment for epilepsy, which the FDA had specifically rejected based on scientific studies that failed to demonstrate efficacy. Likewise, the company promoted Neurontin as effective for treating bipolar disease after a scientific study demonstrated the drug was no more effective than placebo.

According to a DOJ press release, "The state Medicaid programs [Medicare did not provide prescription drug coverage at the time] were harmed by Warner-Lambert's aggressive promotion for off-label uses in numerous ways. The conduct caused doctors to write prescriptions for Medicaid patients when those medications were not eligible for Medicaid reimbursement in that the prescriptions were fraudulently obtained through false statements." Warner-Lambert allegedly used a number of tactics to achieve its off-label marketing goals, including, but not limited to: (1) encouraging sales representatives to provide one-on-one sales pitches to doctors about off-label uses without prior inquiry by the doctors, and (2) "utilizing 'Medical Liaisons' who represented themselves (often falsely) as scientific experts in a particular disease, to promote off-label uses for Neurontin.

### **Schering-Plough Corporation**

In August 2006, the DOJ announced that Schering-Plough Corporation and its subsidiary, Schering Sales Corporation, had agreed to pay \$435 million to resolve criminal charges and civil liabilities in connection with illegal sales and marketing programs for its drugs Temodar and Intron A. The settlement also resolved allegations of Medicaid fraud in violation of the Medicaid Drug Rebate Program for Schering's drugs, Claritin RediTabs and K-Dur.

According to the press release announcing the settlement, Schering agreed to settle its Civil False Claims Act liabilities and liabilities under the FDCA for a total of \$255 million. The civil settlement resolved allegations that Schering "knowingly caused the submission of false and/or fraudulent claims for Schering's drugs that were not eligible for reimbursement." <sup>2</sup> Schering caused the false claims to be submitted by, among other actions, (1) inducing physicians to use Temodar for certain patients with brain tumors and brain metastases and to use Intron A for certain patients with superficial bladder cancer through preceptorships, sham advisory boards, lavish entertainment, and improper placement of clinical trials; and, (2) knowingly promoting off-label uses of Temodar for certain brain tumors and metastases and Intron A for superficial bladder cancer despite not having FDA approval.

Further, Schering pled guilty to charges that it conspired with others to make false statements to the FDA in response to the FDA's inquiry regarding illegal promotional activities by Schering sales representatives at a national medical conference for oncologists.

The false statements were designed to reassure the FDA that the promotional activities were isolated and not directed by corporate headquarters, when in fact, the activities were widespread and part of a national off-label marketing plan.

#### **InterMune, Inc.**

Shortly after the Schering settlement was announced, a biopharmaceutical firm, InterMune Inc., paid the government \$36.9 million in October 2006 to resolve criminal charges and civil liabilities in connection with illegal promotion and marketing activities for an off-label use of its drug, Actimmune. Actimmune was approved by the FDA for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis. However, according to the DOJ press release about the settlement, "the vast majority of Actimmune sales during the period August 2002 through January 2003 were attributable to prescriptions for the treatment of IPF [idiopathic pulmonary fibrosis]." <sup>3</sup>

Further, InterMune had conducted a Phase III clinical trial of Actimmune from 2000 to 2002 that failed to establish statistically significant evidence of benefit for treating IPF. Despite this, the company had issued a press release in August 2002 that said that the clinical trial's results "may extend the lives of patients suffering from this debilitating disease [IPF]" and also stated the drug was the "only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials." <sup>1</sup> An interesting aside is that recently, in March 2007, InterMune reported the early stopping of the INSPIRE study of Actimmune for the treatment of IPF because an interim analysis showed that subjects randomized to receive the drug did not benefit vs. placebo.

#### **Cell Therapeutics, Inc.**

Five months later, the Government entered into a similar settlement with Cell Therapeutics, Inc. ("CTI"). In April 2007, CTI paid \$10.5 million to settle allegations that it caused doctors to prescribe its drug, Trisenox, to treat various forms of cancer for which the drug was neither approved by the FDA nor proven to be either safe or effective. Allegedly, because of CTI's actions, doctors who prescribed Trisenox off-label "unwittingly" submitted false claims for reimbursement to the Medicare program from 2001 until 2005. <sup>4</sup>

Under Medicare rules, Medicare pays for anti-cancer drugs only when prescribed for FDA-approved uses or uses that are listed as medically accepted in certain Medicare designated drug compendia. CTI knew that Trisenox was FDA-approved for only one type of cancer and was not listed as medically accepted for treatment of any other cancer in any of the designated compendia, yet CTI had suggested to physicians that Trisenox was FDA-approved and listed as medically accepted in the compendia for other types of cancers.

#### **JAZZ Pharmaceuticals, Inc.**

The most recent settlement related to the Act not only settled allegations of false claims against federal and state healthcare benefit programs, but imposed liability for criminal restitution to private insurance companies under an expanded authority created by the Health Insurance Portability and Accountability Act ("HIPAA") of 1996. Generally, people think of HIPAA as the federal privacy rule that protects personal health information. However, HIPAA also created federal criminal offences under Title 18 for fraud and theft in connection with the provision of healthcare services and supplies. In the process, it greatly expanded federal jurisdiction over health fraud generally. <sup>5</sup> Most notably, the definition of "healthcare benefit program" expanded federal jurisdiction to fraud perpetrated against private insurers. <sup>6</sup>

On July 13, 2007, the DOJ announced a \$20 million dollar settlement with JAZZ Pharmaceuticals, Inc. to resolve criminal and civil allegations in an investigation of illegal off-label marketing schemes employed by one of its subsidiaries, Orphan Medical, Inc. The

settlement included criminal restitution to public and private insurers of approximately \$12.2 million and a criminal fine of \$5 million. A civil monetary penalty of \$3.75 million plus interest resolved the government's false claims allegations under the Act.

Orphan pled guilty to felony misbranding in violation of the FDCA in connection with its illegal promotion of the drug Xyrem. Xyrem is a powerful central nervous system depressant that has been abused as a recreational drug and is classified by the Department of Health and Human Services ("DHHS") as a "date rape" drug. The drug is approved only for two medical uses: In July 2002, the FDA approved Xyrem for treatment of cataplexy associated with narcolepsy and in November 2005 the FDA approved the additional use of Xyrem for treatment of excessive daytime sleepiness ("EDS") in narcolepsy patients. Xyrem is capable of inducing sleep very quickly and can cause serious side effects. Abuse of the drug can cause dependence and craving, as well as seizures, coma and even death. Further, Xyrem's "black-box" warning label indicates that the drug's safety and efficacy have not been established in children and only limited experience with the drug in the elderly exists.

In pleading guilty to the criminal charges, "Orphan admitted that, through sales representatives and at least one medical consultant, it engaged in a scheme to expand the market for Xyrem by promoting the drug to physicians for 'off-label' medical uses." <sup>7</sup> Allegedly, Orphan induced physicians around the country to prescribe Xyrem for off-label uses, "including fatigue, insomnia, chronic pain, EDS (before it became an approved indication), weight loss, depression, bipolar disorders, and movement disorders such as Parkinson's Disease." The sales force participated in the scheme by making frequent sales calls on physicians who did not specialize in narcolepsy and by distributing written materials regarding the off-label uses that did not adhere to FDA guidance. The subsidiary also admitted that it paid its consultant, a psychiatrist, tens of thousands of dollars for speaking engagements promoting Xyrem for off-label uses. The psychiatrist allegedly made misleading statements about Xyrem in the course of promoting the drug, including minimizing the dangers of Xyrem overdose, suggesting the drug is not a "date rape" drug, and also suggesting that the drug was customary and safe to use in children and the elderly. Further, the psychiatrist allegedly counseled physicians on how to "conceal" the off-label uses in order to secure reimbursement from insurers.<sup>5</sup>

### **Corporate Integrity Agreements**

In addition to the settlements with the DOJ discussed above, all of these companies entered into five-year corporate integrity agreements ("CIAs") with the DHHS Office of Inspector General ("OIG"). The terms of the CIAs are for the most part identical, which isn't surprising given the overall similarity of the fraudulent conduct. The CIAs are interesting in respect to some of the requirements imposed on these companies with regard to conducting future clinical trials.

For example, the companies are required to establish written policies and procedures addressing compliance with "all applicable federal healthcare programs and FDA requirements" when sponsoring or funding "research activities (including clinical trials, market research, or authorship of articles or other publications)." In addition, the policies must "ensure that sales and marketing activities are separate from clinical trial enrollment." All persons covered under the CIA must receive training and education on (1) required policies and procedures; (2) all relevant and applicable FDA regulations and federal healthcare program requirements; and, (3) in general, "the proper methods of promoting, marketing, selling, and conducting research (including clinical trials)."

Another noteworthy requirement is annual certification by the companies' compliance officers that policies and procedures, templates for standardized contracts and similar documents, training materials and promotional or educational materials about products

“have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws.”

### **Clinical Trial Sponsors Beware**

False claims are no longer just “hospital billing problems.” With growing government antifraud budgets and whistle-blower information to guide them, government regulators are increasingly scrutinizing business practices in the pharmaceutical industry and holding pharmaceutical companies accountable for causing providers to submit false claims by either withholding information (e.g., results of failed clinical trials) or “suggesting” that an off-label use is billable to federal health programs. In the words of one U.S. Attorney, “The pharmaceutical industry will not be allowed to profit from such conduct [promoting off-label use] nor subject the poor, the elderly and other persons insured by state and federal health programs to experimental drug uses which have not been determined to be safe and effective.”<sup>8</sup>

On the other hand, Medicare has covered certain investigational devices and costs associated with surgical implantation of the devices since 1995 and “routine” items and services rendered during qualifying drug trials since 2000. These rules are an attempt to increase Medicare beneficiaries’ participation in clinical trials. However, along with the good usually comes the bad. Numerous hospitals and academic medical centers have since entered into settlement agreements for improper billing practices under these rules.

The false-claims risk for sponsors of clinical trials primarily arises in the form of erroneous “billing guidance” with respect to the investigational item or service as well as other medical care items and services required by the protocol. The erroneous guidance can be deliberate or unintentional and may appear in the clinical trial agreement (“CTA”), sponsor template, consent form, other supporting documentation (e.g., separate coding and billing guidance), and possibly even in the protocol itself.

### **Device Trials**

An example of perhaps unintentional erroneous guidance can be found in a device manufacturer’s CTA exhibit with regard to compensation and payment terms: “The FDA has classified [device] as a Category B device.... As a Category B product, [device] and related procedures are eligible for reimbursement by Medicare and many commercial payors.” It is common in the industry to misinterpret the 1995 interagency agreement between the FDA and Medicare (aka “Category B Regulations”) as providing coverage for any device classified as a Category B by the FDA.<sup>9</sup> However, devices assigned to Category B are not automatically covered or billable to Medicare; the underlying procedure itself must first be covered for the disease or condition under study. In addition, prior approval of local Medicare contractors is also required in most geographic areas.

Moreover, under Medicare’s “related to, not related to” rules, if an underlying implant procedure is not covered, services “related to” the noncovered service are also not covered, including pre- and post-implant items and services. Thus, even if the sponsor provides the noncovered device at no charge, statements in the template consent form and/or CTA suggesting that pre-diagnostic workups and post-implant follow-up are standard-of-care and should be billed to third-party payers could also be viewed as encouraging or “causing” false claims. The following is an example of such language found in a sponsor’s template consent form:

As a participant in this study, you or your insurance company will not be responsible for the costs of research-related activities. The [device] and surgical implant will be

provided at no charge to you or your insurance company. The rest of the medical care that you receive is considered standard-of-care for your situation and thus would be performed regardless of your decision to participate in this study. These costs will be billed to you or your insurance carrier.

## Drug Trials

Device manufacturers aren't the only ones venturing into dark waters. Although investigational drugs that have not been approved by the FDA for any use are typically provided free of charge, FDA-approved drugs being studied for an "off-label" use may or may not be. Unless the off-label use under study is listed as medically accepted in Medicare-recognized drug compendia, the investigational drug should not be billed to Medicare.

Unlike the regulations governing device trials, Medicare may cover items and services "related to" non-covered drugs. The National Coverage Determination ("NCD") for Routine Costs in Clinical Trials<sup>10</sup> (now renamed and referred to as the "Clinical Research Policy") provides coverage for medically necessary and reasonable items and services needed to monitor the effects of the investigational drugs and/or to prevent complications associated with the drugs. However, Medicare does not cover items and services primarily used for research purposes or data collection. The distinction between "medically necessary and reasonable monitoring" and "primarily for research purposes or data collection" can be a fine line and is a source of confusion for many in the healthcare industry. Regardless, as in device trials, there is plenty of language in consent forms and CTAs stating that some or all of the diagnostic services required by the protocol are "considered standard-of-care" or "would be performed if you were not participating in a clinical trial." In some cases this information is correct; in others it is not.

Diagnostic tests are especially vulnerable to allegations of false claims:

- **Diagnostic tests used to determine eligibility that must be performed within the protocol-defined "screening" window.** "Piggy-backing" on the results of a routine test previously performed and billed should not be a problem, but if the test has to be repeated solely to meet the screening window, it should not be billed to third-party payers.
- **Primarily research-oriented procedures, such as laboratory tests and other diagnostic services.** If the results of the tests are "blinded" to the investigator and/or not otherwise used in the direct medical management of the patient per the protocol, they are not considered medically necessary and reasonable for purposes of billing federal and state healthcare programs.
- **Items and services required to meet a secondary objective of the protocol.** For example, an FDG-PET scan should not be billed in addition to a CT scan if one of the secondary objectives of the study is to determine if PET scans are superior.
- **Repeat "confirmatory" diagnostic tests required by the protocol "in order to document partial or complete response."** Generally speaking, unless the results of a previous diagnostic test are inconclusive, Medicare should not be billed for repeat testing.
- **Follow-up diagnostic services exceeding healthcare standards in frequency or duration.** For longer-term follow-up, healthcare guidelines may provide for diagnostic services "as clinically indicated." In that case, one would be hard pressed to argue that diagnostic tests every three months for two years are routine care.

- **Diagnostic tests that must be performed at an “early termination visit.”**  
Depending on the reason for the subject’s withdrawal and timing of the early termination visit, these services could be viewed as “primarily research-oriented” or duplicative of services recently performed as routine follow-up (e.g., tumor assessments).

Sponsors offering guidance on what is standard-of-care in their CTAs or template consent forms typically try to limit their liability or shift it to research sites by including contract provisions that state that the sites are “ultimately responsible for determining and submitting appropriate codes and charges for the services rendered.” Yet, these same sponsors attempt to make themselves the payers of last resort by providing payment for items and services only after the provider receives multiple denials. For purposes of the Act, it is a violation to knowingly submit a false claim or cause one to be submitted. The Act does not come into play only if the false claim is ultimately paid.

So far, false claims settlements involving improper billing in clinical trials have been isolated to individual research sites. However, it is not inconceivable that if one site in a multi-site trial relied on a sponsor’s erroneous billing guidance other sites may have as well. Government regulators and potential whistleblowers need only search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) to obtain a list of all participating sites, but why go through the effort and expense of pursuing each site individually when an argument could be made that the deep-pocketed sponsor “caused” the submission of the false claims?

### **The 3 C’s: Communication, Collaboration and Coordination**

Clinical trials involve a complex set of interdependencies among all stakeholder organizations: sponsors, contract research organizations (CROs), clinical investigators, and research sites. Any regulatory enforcement action, even if successfully defended, exposes all stakeholders to public disapproval and perhaps lost revenue. Stakeholder organizations involved in clinical trials not only need to strengthen internal policies and procedures, but develop better lines of communication, coordination and collaboration among stakeholder organizations to ensure mutual compliance and protect their respective reputations. False claims exposure to study sponsors may occur if communication is limited.

Prior to developing study budgets and template consent forms, sponsors should consider working with specialized reimbursement experts to conduct an initial coverage analysis for all items and services required by the protocol. Coverage analysis uses a methodology that ensures equitable and legal distribution of costs among: (1) sponsors, including federal and state agencies; (2) third-party payers, including federal and state healthcare programs; and, (3) subjects. As a side benefit, coverage analysis eliminates any billing ambiguities in the study budget.

A coverage analysis based on thorough research of applicable regulations and supported by healthcare guidelines meeting the standard of “generally accepted in the medical community” goes a long way towards protecting against allegations of false claims. Although Medicare/Medicaid coverage is not “black and white” and mistakes can get made, a coverage analysis with supporting documentation shows “careful consideration” as opposed to “reckless disregard” or “deliberate ignorance.”

Sponsors should provide their proposed study budgets to potential sites based on this initial coverage analysis and not leave it up to individual researchers, who may not be savvy enough in billing regulations to allocate sponsor payments amongst research-related activities and patient-care items based on sometimes ambiguous study budgets and contracts. For example, “per capita” payment structures, along with contract provisions stating that the payments cover both research-related activities and undefined “non-

standard of care items” could lead to inconsistency in billing. Different billing practices across research sites are susceptible to retrospective second-guessing by government auditors and, therefore, should be avoided.

Any budget line item that appears high, especially in comparison to other payment items in the trial, invite suspicion that the “overpayment” constitutes double-billing (i.e., a false claim) for some charge to a government payor. Similarly, lump-sum visit payments that do not assign fees to specific activities open the door for the Government to allocate payments in a way that creates the appearance of double-billing.

This is not to say the sponsor must take all responsibility. Unfortunately, Medicare coverage can vary among geographic regions, especially in coverage of investigational devices, which is somewhat left to the discretion of local Medicare contractors. Further, Medicaid coverage varies from state to state. Some states do not cover any services rendered as part of a clinical trial while others have vaguely worded regulations about what is considered “experimental” and thus, noncovered. At the other extreme, a handful of states do consider what Medicare and other third-party payers cover.

Research sites should be familiar with Medicare and state Medicaid program coverage in their regions. In some cases, they are responsible for obtaining prior approvals before billing occurs. Prior to completing contract negotiations, research sites should conduct a more-detailed analysis of the trial based on local coverage in the states from which the subject population is expected to be drawn. Because many sites are unaware of these responsibilities, study sponsors should include a notification in the CTA, to minimize the risk of getting sucked into an enforcement action.

Further, sites should also review the terms of managed care contracts and coverage policies of their largest commercial payers to get an overall understanding of coverage for investigational services. However, this review cannot substitute for the pre-certification or pre-authorization process required by most commercial payors.

The Government has built a record of lucrative enforcement actions against pharmaceutical and medical device companies that “cause” violations of the False Claims Act. Clearly, sponsors of clinical trials should not feel immune from prosecution just because they do not bill federal and state health programs directly. That line of reasoning certainly did not protect the six companies mentioned above. The media drumbeat, fair or not, about questionable industry behavior in clinical trials may entice whistle-blowers and enhance the political appeal of enforcement actions. Clinical trial sponsors should proactively address their potential risks and liabilities under the Act to avoid becoming the next enforcement target.

Given the complexity of the regulatory environment surrounding clinical research and the enormity of conducting a full-scale risk assessment, it is difficult to know where to begin. However, communication, collaboration and coordination among all stakeholders, as well as within stakeholder organizations, one trial at a time, is probably just as good a place as any to start.

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