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NEGOTIATING FALSE CLAIMS ACT SETTLEMENTS

By Jonathan Cone, Robert Rhoad, and Robert Sneckenberg

Twenty years ago, one commentator observed that while False Claims Act (FCA)[1] settlements were common, it was impossible for practitioners to find a standard settlement agreement:[2]

> The rapidly increasing number of False Claims Act claims, both *qui tam* and brought by the Department of Justice ("DOJ"), has focused the attention of the DOJ and the defendants on the terms and conditions of settlement agreements. The Civil Division of DOJ is attempting to standardize the terms of these agreements. There are, to our knowledge, no publicly available materials setting forth the DOJ's position on settlement agreements.

The above words may as well have been written yesterday. The FCA has become the U.S. Government's weapon of choice in combating fraud on the public fisc and in pursuing recovery of ever-increasing sums—$3.8 billion in 2013 alone.[3] Yet, while it is well known that the vast majority of funds that the Government recovers under the FCA are obtained through settlements, little has been written about the process by which such settlements are negotiated and, ultimately, crafted.

This BRIEFING PAPER presents an overview of some of the key provisions in FCA settlement agreements between defendant corporations and the Government, as well as guidelines for defendants seeking to obtain a broad release and to reduce their continuing exposure. The authors have reviewed countless settlement agreements from the past five years to cull examples to assist in the drafting and negotiation of agreements going forward.[4] While in some instances the Government

IN BRIEF

Robert Rhoad is a partner, Jonathan Cone is a counsel, and Robert Sneckenberg an associate, in the Washington, D.C. office of Crowell & Moring LLP. All authors are members of the firm's Government Contracts practice group and focus on procurement fraud cases. Mr. Rhoad and Mr. Cone are also members of the firm's White Collar & Regulatory Enforcement practice group.

may plant its feet firmly in the ground and refuse to negotiate provisions—such instances will be noted—in others there is a significant opportunity to draft a broad settlement agreement to protect a defendant's interests. This PAPER first addresses the most critical aspects of FCA settlements that defendants can, and should, negotiate—the covered conduct, denial of liability, and scope of release—then describes a few less common provisions in FCA settlements, and concludes by noting some of the provisions that are generally not subject to negotiation. The aim of this PAPER is to provide anyone faced with a potential FCA settlement a working knowledge of the primary considerations in drafting such agreements and creating an effective release of future liability.

The "Covered Conduct"

In 2012, Wells Fargo Bank N.A. paid $5 billion to the United States to settle allegations that it engaged in misconduct in making Federal Housing Administration-insured mortgage loans. As part of the settlement, Wells Fargo signed a consent judgment with the United States, in which the United States agreed to release the bank from violations of the FCA related to false or fraudulent *annual certifications* of compliance with FHA regulations. But, only a few months later, the United States sued Wells Fargo again, in a different court, for violations of the FCA based on—*déjà vu!*—conduct *underlying* its annual certifications of compliance with FHA regulations.[5]

Although Wells Fargo is appealing the new case's validity—a district court has already held that the second suit is not barred by the earlier consent judgment[6]—the bank's predicament is a reminder to anyone settling FCA cases that doing so is not a routine matter, but one with many traps for the unwary. Each provision must be carefully scrutinized and understood. But no clause is more important than the definition of "covered conduct"—which describes the allegedly improper conduct that is being released by the Government—because this is what establishes the metes and bounds of the agreement. Only that conduct explicitly defined by the agreement as the "covered conduct" will be released; conduct that is not included is not released and is, as Wells Fargo regrettably discovered, subject to more litigation and a risk of future liability.

The goal for every FCA defendant, then, is to negotiate the broadest possible release by writing the broadest definition of covered conduct. But it is not enough when doing so to merely define those claims that the Government did bring—or threatened to bring if no case was filed. It is equally important, if not more so as the Wells Fargo case shows, to anticipate what other conduct could be the subject of investigation or litigation, by either the Government or a *qui tam* relator, to ensure that the agreement will bar a later lawsuit related to the same or similar conduct. While each case is different, making it impossible to write a standard definition for covered conduct that will apply in every case, the following examples, taken from actual DOJ settlements, illustrate possible ways of crafting a favorable definition of covered conduct.

■ Be Detailed, But Not Too Detailed

One way to craft a broad release is to be very specific and detailed in describing the conduct in which the company or individual was alleged

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to have engaged. Although describing unlawful conduct in detail may be counterintuitive and hard to stomach, especially when a settling party believes the allegations are unfounded, being detailed can make the release more certain and less ambiguous. This type of release is often seen in the context of healthcare settlements. For example, when GlaxoSmithKline LLC (GSK) agreed to pay over $1 billion—as part of a $3 billion global settlement of criminal and civil claims—to resolve allegations that it promoted off-label uses of pharmaceutical products that had not been approved by the U.S. Food and Drug Administration (FDA), its agreement described the covered conduct in detail:[7]

> Wellbutrin: During the period January 1, 1999 through December 31, 2003, GSK knowingly: (a) promoted the sale and use of Wellbutrin for conditions (including weight loss, the treatment of obesity, sexual dysfunction and in combination with other anti-depressants) and at dosages other than those for which its use was approved as safe and effective by the FDA, and some of which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Wellbutrin; (b) made and/or disseminated unsubstantiated and/or false and/or misleading representations or statements about the safety and efficacy of Wellbutrin; and (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Wellbutrin, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). As a result of the foregoing conduct, GSK knowingly caused false or fraudulent claims for Wellbutrin to be submitted to, or caused purchases by Medicaid and the other Federal Health Care Programs.

After reading this paragraph, there is little doubt about the exact conduct that is being released, including the time period covered. That brings certainty and clarity to the agreement, guarding against future claims based on allegations involving the same drug, Wellbutrin. But clarity comes at a cost: there is no room for GSK to argue that the release applies to a drug other than Wellbutrin (although claims related to several other drugs were released in the agreement) or even to GSK's marketing practices for Wellbutrin in a later time period, i.e., after 2003. Although the agreement—costing over $1 billion—was clear, it was not broad. This was certainly a decision the company made based on the circumstances of the settlement negotiations and its own risk tolerance.

There are a few methods by which a settling party may craft a release to avoid having too much specificity, thereby broadening the scope of its coverage. One method is to explicitly include all allegations that were made in the Government's complaint or the relator's *qui tam* complaint. A recent DOJ settlement with FedEx Corporation illustrates this approach.

In 2006, FedEx was sued by a *qui tam* relator, who at the time was a FedEx employee, for allegedly submitting false claims under contracts for delivery services with various federal and state agencies.[8] The crux of the relator's complaint was that FedEx, in the aftermath of the September 11, 2001 terrorist attacks, misused a certain delivery code—reserved for delays that were due to increased security measures that its couriers faced entering Government buildings—to excuse its failure to make on-time deliveries. The relator alleged, for example, that when FedEx failed to meet the delivery deadline for "Priority Overnight" deliveries, it would miscode the delivery to avoid making it appear late. She alleged that entire truckloads of FedEx packages were designated as having been delayed due to a security delay even before the trucks had left FedEx's facility.[9]

After investigating the relator's allegations, the United States negotiated a settlement with FedEx, without filing its own complaint in intervention. The settlement agreement, like GSK's settlement, contained specific allegations of the misconduct that was being released. But it also released all of the allegations that the relator had made in her complaint, without limitation:[10]

> The United States contends that it has certain civil claims against FedEx arising from FedEx's misuse of the DEX 5 "security delay" code as well as misuse of the DEX 8 "customer not in" and DEX 24 "recipient unavailable" delivery exception codes in conjunction with deliveries to government facilities between January 1, 2002 and the Effective Date of this Agreement....This conduct, along with the conduct alleged in the *qui tam* complaint in the civil action, is [released].

FedEx not only obtained a release of the Government's claims, but also resolved the allegations that the relator had made, barring her or anyone else from recovering for the same claims. Given the breadth of the relator's complaint—she alleged that a large percentage of FedEx's business was with federal, state, and local governments, as well as other Government contractors—this was a remarkably broad agreement. But, notably, the Government had not intervened. Had the Government done so, the settlement agreement may have been more narrowly tailored to match only the allegations in the Government's complaint. This is one reason to settle *qui tam* cases early, before the Government files a complaint in intervention, which may limit the scope of any later settlement.

Although the authors of this Paper are not aware of an official DOJ policy on point, the standard practice once the Government has filed a complaint or complaint in intervention, apparent from the settlement agreements we reviewed, is for the DOJ to limit any settlement to those allegations found in the four corners of its complaint. For example, the DOJ structured a settlement agreement, following a complaint in intervention, with a collection of healthcare providers and healthcare organizations as follows:[11]

> The United States and the State of Missouri contend that they have certain civil claims…against Defendants for engaging in the conduct described in the Complaint in Intervention filed in the Civil Action (hereinafter referred to as the "Covered Conduct").

But this limitation on settlements following a complaint or complaint in intervention is not necessarily a bright-line rule. The Government has, on occasion, included conduct in the release that was not also in its public complaint. For example, when the Government recently settled an FCA case with a healthcare organization and provider, it used the following release:[12]

> The United States contends that it has certain civil claims against defendants…for engaging in the conduct alleged in the United States' Complaint filed on October 16, 2009 and for the defendants' improper billing of the following codes on behalf of the MIMA Cancer Center and Osler Medical from 2003 through 2008; CPT Codes 77431-432, 77435, 76950, 77413-416, 77263, 99212-254, 77470, 76872, J0207, 96401 (hereinafter referred to as the covered conduct.

Thus, settling companies should attempt, if possible, to broaden the covered conduct beyond the allegations in any Government complaint.

■ Cover Specific Contracts

A second method of broadening an agreement's scope—especially for Government contractors—is to identify the contracts, task orders, or delivery orders that are being released. Rather than specifying the conduct that is covered, identifying the contracts at issue can in some instances be more effective because it will include any claims for payment that were submitted under those contracts, task orders, or delivery orders. This can be done by citing the specific contract number or, more helpfully, by referencing all contracts that the settling party had with the Government or agency.

A good example of this approach is a recent settlement that the Government executed with Educational Testing Services (ETS), a nonprofit company that administers tests used for college and graduate school admissions, such as the Test of English as a Foreign Language and Graduate Record Examinations. In 2011, ETS inked a settlement with the Government to resolve allegations that it had improperly charged the U.S. Department of Education for retiree medical benefits related to a medical trust that the company had earlier stopped funding. Rather than limit the agreement to specific charges or invoices, the Government released all charges that were made on any of ETS's contracts with the Department of Education:[13]

> The United States contends that it has civil causes of action against ETS…arising from allegations…that ETS…during the period 1999 to 2008, improperly billed the Department of Education for unfunded post-retirement medical benefits on contracts ETS had with the Department of Education (hereinafter referred to as the "Covered Conduct".)

Although this release language is broader than most, because it is not limited to a subset of contracts, task orders, or delivery orders, it was not a blanket release for ETS because it was still tied to postretirement medical benefits that were billed to the Government. Nothing would prevent the Government, in other words, from pursuing a case against ETS for its work under the same contracts based on different alleged misconduct.

In healthcare cases, this approach may entail the listing of codes or patients for which false claims may have been submitted. In such cases, the Government may include an appendix of all patients who received medical care that was billed to a Government healthcare program. For example, when the Government settled a case with Hospice Family Care, Inc. (HFC), which provided hospice care in Arizona, the settlement agreement listed by initials, locations, and dates of service the 152 patients on behalf of whom claims had been submitted to Medicare. The Government alleged that claims submitted on behalf of these patients were false because they were either hospice ineligible or received a higher level of hospice care than was necessary:[14]

> The United States contends that it has certain civil claims against [defendants] based upon a review of the medical files of the HFC patients identified in Exhibit 1, attached hereto and incorporated herein by reference. The United States contends that [defendants] submitted claims for payment to the Medicare Program for these patients, identified at Exhibit 1, some of whom were either completely or partially hospice ineligible or were provided a higher level of hospice care than was necessary or allowable. That conduct is referred to below as the Covered Conduct.

Similar to the contract-listing method, referencing or incorporating an appendix in such situations can ensure that all relevant conduct is covered.

■ Cover Investigations

A third method for broadening an agreement's scope—which is rarely used, but is worth considering—is to release all conduct or allegations that the Government investigated but declined to pursue. This may in some situations be a fairer outcome. When the Government has had an opportunity to fully investigate allegations of wrongdoing, but has found no evidence of misconduct, it may be open to considering a release of all claims based on those allegations, especially if the settling party itself first disclosed the allegations to the Government, cooperated in the Government's investigation, and then voluntarily strengthened its internal compliance and training programs. This would for the settling party bring finality to the Government's investigation and foreclose future parasitic suits. But, alas, this is rarely done. Nearly every settlement agreement we reviewed limited its definition of covered conduct to specific allegations of wrongdoing.

One exception, however, involved a settlement between the Defense Logistics Agency and TW Metals, Inc. According to the agreement, TW "sold certain items of metal and specialty metal…to the Department of Defense that did not conform to domestic source restrictions," such as the Berry Amendment, the Buy American Act, and the Trade Agreements Act. According to the DOJ's press release, TW voluntarily disclosed to the DOD that it may have supplied nonconforming metals, investigated its own direct and indirect contracts with the Government, made additional disclosures, and instituted a series of compliance measures to ensure compliance with domestic preference statutes.[15] TW later signed a settlement agreement with the Government. As part of this agreement, the Government agreed to release TW for metals that were provided under any contract that the Government had investigated:[16]

> "Covered conduct" means TW Metals' failure to comply with domestic source restrictions in the following contracts: Contract Nos. SPO500-01-D-0172, SPO500-01-D-BPO3, SPO500-05-D-0146 and any other contract, subcontract, purchase order, or agreement…whether that Contract was direct with the federal government or indirect with a prime contractor or higher tier subcontractor who sold to the federal government insofar as that Contract was investigated and examined in connection with TW Metals' Voluntary Disclosure….

This agreement is unusual because the Government agreed to release TW not only for specific contracts, but for "any other contract, subcontract, purchase order, or agreement" that may have been swept into the Government's investigation. Although this is somewhat vague—after all, who but the Government knows the full extent of its investigation—it certainly gives TW much more comfort than a typical settlement, which only lists one or two "covered" contracts. The Government's willingness to do so may be explained by TW's voluntary disclosure and cooperation in the Government's investigation.

■ Get Your Timing Right

Regardless of how you describe the conduct or claims at issue (e.g., narrowly, broadly, by contract), nearly every FCA settlement agreement lists the specific time period for which claims are being released. Any organization or individual settling with the Government should seek the broadest period of time for their release. A good agreement will ensure that any claims for the same conduct being released will be completely barred, up until the date the agreement is signed, by the release itself and the FCA's statute of limitations, which is normally six years.[17] To do this, two factors are important.

First, the definition of covered conduct should include all conduct occurring up and until the date of settlement. There is no reason to pick an arbitrary date before the settlement agreement is signed, unless you are sure there is no exposure for that period and no other *qui tam* complaints have been (or might be) filed. Instead, make the time period covered by the agreement match the date of settlement, ensuring the agreement leaves no wiggle room for the Government or a copycat *qui tam* relator to pursue allegations of the same or similar nature in a different time period. Surprisingly, most agreements do not do this. But there are a few agreements that do, such as the FedEx agreement quoted above[18] and a University of Phoenix settlement agreement executed in 2009:[19]

> For purposes of this Agreement, "Covered Conduct" shall mean any conduct relating to the University of Phoenix's compliance or noncompliance with the incentive compensation provision, 20 U.S.C. § 1094(a)(20), and/or the Department of Education's associated regulations, 34 C.F.R. § 668.14(b)(22), from March 1997 to the Effective Date of this Agreement.

Second, the time period covered by the release should go far enough back in time so that any possible claims before that date would be precluded by the FCA's normal six-year statute of limitations. Although there may be some exceptions to the standard statute of limitations—such as the Wartime Suspension of Limitations Act[20]—the agreement should at least cover this time period, unless there is no reason to fear allegations of wrongdoing before then—i.e., the contract was not awarded until a specific date.

■ Avoid Ambiguity

Finally, no matter what language you use, make sure the definition of covered conduct is not so ambiguous that it could allow the Government or a creative *qui tam* relator to file a second FCA case based on the claims or allegations that you thought were already settled. The Wells Fargo case discussed earlier in this Paper is a good example of this problem.[21]

The Denial Of Liability

It may seem counterintuitive, but once a company has fine-tuned the conduct for which it is buying a release, it needs to go back and point out that it never actually engaged in that conduct! An FCA settlement is not a criminal guilty plea—the defendant need not, and should not, admit to having violated the FCA (or any other statute, regulation, or obligation). After all, any FCA claim involves a certain element of litigation risk that is avoided by a settlement agreement. Whether a company regards its risk as high or low, the Government's case is hardly ever a slam dunk, so it need not concede as much. With that in mind, here are a few helpful hints for how to make it clear that the defendant does not admit to any wrongdoing.

■ Deny All Liability

The first step—denying liability—is simple, but, as with most settlement provisions, there are options. The most straightforward way to deny FCA liability is to include a statement that the settlement is made in compromise of disputed claims and that neither party concedes anything. For example, the following language (or minor variations thereof) is common in FCA settlements:[22]

> This Agreement is neither an admission of liability or wrongdoing by the Defendants nor a concession by the United States that its claims are not well-founded.

While the above language gets the point across that the defendants disagree with the allegations, occasionally defendants wish to be more forceful in their denial of liability. Thus, another option is to deny each specific allegation made by the Government (or *qui tam* relators) or made against individual defendants or entities. For example, pharmaceutical giant AstraZeneca opted for the following denial provision:[23]

> This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by AstraZeneca nor a concession by the United States that its claims are not well founded. AstraZeneca expressly denies the allegations of the United States, the Medicaid Participating States, [and relators] as set forth herein and in Civil Action I and Civil Action II and denies that it has engaged in any wrongful conduct. Neither this Agreement, its execution, nor the performance of any obligation under it,

> including any payment, nor the fact of settlement, are intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by AstraZeneca.

The AstraZeneca denial is certainly more forceful than a basic recitation that neither party concedes the validity of the opposing party's claims. There may be no additional legal significance or protections associated with such a denial—e.g., unallowable cost implications are often nonnegotiable, as discussed below—but such a precise denial may serve other goals such as smoothing concurrent negotiations with other administrative or suspension and debarment officials, or even managing public relations and the appearance of wrongdoing. Shareholders, for instance, may view a company as having more seriously considered or investigated allegations where each allegation is addressed, and denied, with some specificity, as opposed to with a blanket denial.

The important thing to remember, though, is that when a defendant denies liability, it must do so completely. If it chooses to deny specific allegations, it needs to make sure it denies each and every aspect of the covered conduct. It cannot get so bogged down denying one specific allegation that it forgets to catch everything or forgets to include a catch-all clause denying any additional allegations related to the covered conduct. The trees are important, but settling parties must remember the forest.

■ Coordinate With Other Settlements

This Paper assumes, for the most part, that the FCA settlement is occurring in a vacuum. But, oftentimes, that is not the case. The same (alleged) conduct that gave rise to potential FCA liability may well have engendered criminal or administrative liability or implicated concerns such as suspension and debarment. While the FCA settlement itself cannot resolve all of these matters—though one could pursue a global settlement strategy with multiple contingent, coordinated settlements, pleas, and agreements—a settling defendant must keep them in mind when negotiating the FCA settlement.

One of the key crossover points between the FCA settlement and other concerns will be in the denial of liability. Assuming that the same covered conduct (with the same description) is at the heart of the other concerns, the way in which a defendant denies any FCA liability may well depend upon or affect its other issues. For example, in a scenario in which the defendant is concurrently settling a criminal matter by pleading guilty to a reduced charge (or accepting a reduced penalty), its FCA settlement cannot state that it has done nothing wrong at all. But, the defendant can qualify a denial by disclaiming any FCA wrongdoing, even in the face of admitting criminal or other misgivings. For example, Cephalon Inc. crafted the following exhaustive denial of FCA liability notwithstanding a concurrent criminal case:[24]

> With the exception of such admissions that are made in connection with any guilty plea by Cephalon in connection with the Federal Criminal action, Cephalon expressly denies the allegations of the United States and the Relators as set forth herein and in the Civil Actions and denies that it has engaged in any wrongful conduct in connection with the Covered Conduct.

Such language allows for a robust denial of FCA liability, even where the settling defendant may elsewhere admit to liability.

The concerns of crafting broad FCA denial provisions also arise where defendants could be subject to exclusion from or restrictions on future contracting with the Government. In the healthcare context, there are a host of administrative and regulatory requirements with which companies must comply. Any violation related to such requirements may independently (or when combined with FCA liability) implicate administrative liability or concerns. Similarly, regardless of the financial hit from past FCA violations (one would hope that any problems were remedied by the time of settlement), suspension and debarment pose significant continuing threats to defendants settling FCA actions. Depending on a company's relationships with its primary Government customers and agencies, it may be wise to keep them abreast of a pending FCA action or settlement and to notify them when such action has been settled with a full denial of liability. While a Government suspension and debarment official may still be interested in the underlying conduct, the fact that the FCA settlement was entered into without any admission of liability could help to avoid suspension and debarment or other penalties.[25]

The Scope Of Release

After explaining exactly what happened, and then declaring that it did not happen, it is important to determine who may or may not be liable and how they may or may not be liable. Stated more plainly, the settlement needs to clarify the entities—i.e., the defendants, companies, individuals, etc.—and legal theories being released. In certain circumstances, specific business entities or individuals will be directly implicated in the alleged fraud—e.g., the doctor who forged his timecards; the manager who failed to properly monitor his subordinates' billing practices; and the business division or subsidiary wherein the alleged fraud occurred. But, even where the connections are not so obvious, a settling defendant may still have a significant interest in protecting all of its business entities and connected individuals. The best practice is to negotiate as broad a release as possible, covering specific entities and individuals and employing catch-all language to forestall potential future liability.

■ Release All Entities

No two corporate structures are identical. Thus, when it comes to releasing a corporate defendant, the release must cover every version or aspect of that corporate defendant that may, in one way or another, be liable for the covered conduct. Be there parent, brother, or sister corporations, direct or indirect affiliates or subsidiaries, or divisions, successors, transferees, heirs, and assigns,[26] the release can and should identify or describe by affiliation any and all entities that may be liable, individually or collectively. Regardless of whether such entities are listed as defendants in a Government or a *qui tam* complaint (or were investigated for the covered conduct), the settling company must consider its organizational structure and draft accordingly.

■ Release Individuals

The same principle holds true for individuals. Whether or not they are named in a complaint or specifically investigated, settling companies may have an interest in safeguarding their individual employees and executives. While a company may not wish to protect an employee who deliberately mischarged the Government, it may have significant interests in protecting other individuals from potential liability (e.g., the company may be required to indemnify its employees from potential FCA liability). While those individuals may retain independent counsel, oftentimes the company can incorporate specific releases of individuals into the FCA settlement agreement. For example, the following releases serve to protect a host of individuals, identified by name, category, or title:

(1) releasing "officers, trustees, current employees, and those who were employed at the time of the Covered Conduct"[27];

(2) releasing "current and former trustees, directors, officers, agents, representatives, successors and assigns"[28];

(3) releasing "current or former subsidiaries, affiliates,…members,…officers, directors, employees, and agents and the successors and assigns of any of them"[29]; and

(4) releasing "current or former directors, officers, agents, servants, and employees, and their successors and assigns."[30]

It is not always possible to secure such a broad release of individuals—occasionally the Government refuses to release any individual liability[31]—but, as these provisions demonstrate, such releases can often be negotiated and foreclose additional liability.

■ Protect Your Release

While a broad release of all possible entities and individuals may be ideal for the settling defendant, the Government has contrary interests and would like to preserve its potential future claims—be they distinct claims or identical claims asserted against distinct entities or individuals. Aside from simply refusing to negotiate a broad release, the most common way the Government preserves liability is through specifically reserving or excluding claims against individuals. The release provision in every settlement agreement operates in tandem with a specific reservation or exclusion provision, such as the following:[32]

> Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including [defendant] and the Relators) are the following claims….

The reservation provision is nearly always called out directly in the release provision itself with a preface such as: "Subject to the exceptions in Paragraph [x] below (concerning excluded claims)…."[33]

The Government's reservation of claims provision can limit the scope of the agreed-upon release and, where the settling defendant is not vigilant, can even swallow whole portions of the release. In some of the settlements that we reviewed, the reservation provision appears to directly conflict with the release provision, and thus could potentially negate the entire release of individuals' liability. For example, Novartis Pharmaceutical Corporation and Cephalon Inc. each negotiated settlement provisions that purportedly released "current and former directors, officers, and employees," but the settlements also specifically *reserved* "any liability of individuals."[34] Settling defendants must constantly remember the interplay between the various settlement provisions to avoid such direct conflicts and the unraveling of what should be a tight-knit release.

Notably, in recent years the Government has also been making what we refer to as "target letter" reservations, whereby the Government specifically reserves potential civil or administrative claims against any individuals who are subsequently criminally charged or convicted for actions relating to the covered conduct, or who even receive a letter notifying them that they are the subject of such a criminal investigation—i.e., a "target letter." A typical example of a "target letter" reservation specifically reserves and excludes:[35]

> Any liability of individuals (including current or former directors, officers, employees, or agents of [defendant]) who receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement related to the Covered Conduct.

Though seemingly innocuous enough, "target letter" reservations can have a significant impact on the scope of individual liability. They transform otherwise released liability into liability that is perpetually contingent on the mere sending of a letter referencing an investigation, even if the investigation ultimately yields nothing. This is not to say that the Government would send such a letter solely to resurrect otherwise released civil or administrative liability, but rather to highlight that a release subject to a "target letter" reservation may not be as effective as originally thought.

The key point to remember about the Government's use of "target letter" and other reservations is that a settling defendant must consider the entire agreement as a whole and the interconnection between its various provisions. If drafted carefully, the release agreement can be a tight-knit web of security from future liability. But, if overlooked, other provisions can easily unravel that web and open the door to continuing risk.

■ Release Alternative Legal Theories

Along with releasing as many entities and individuals as possible, a settling defendant should attempt to release as many potential claims as possible. Though the focus of the settlement may be on the FCA, there are a host of other statutory, regulatory, and common-law obligations that may be implicated by the covered conduct—e.g., the Civil Monetary Penalties Law, 42 U.S.C.A. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C.A §§ 3801–3812; the Contract Disputes Act, 41 U.S.C.A. §§ 7101–7109; any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, Section 0.45(D); common-law theories for breach of contract, payment by mistake, unjust enrichment, and fraud; and statutory, regulatory or common-law theories of setoff, offset, withholding, or contract debt. Oftentimes such alternative theories of liability will be raised in the Government's or relator's initial complaint, in tandem with the FCA allegations. But, regardless of whether they have yet been raised, a settling defendant should consider potentially applicable alternative theories of liability. The following is a good example of a broad release that you should try to negotiate, depending on your peculiar circumstances:[36]

> [T]he United States…agrees to release [defendant]…from any civil or administrative or monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, Section 0.45(D); or the common law theories of payment by mistake, unjust enrichment, fraud, disgorgement of illegal profits, and, if applicable, breach of contract.

Depending on your situation, some of these theories may not be applicable—and the Government and relators may have no intention of bringing such future claims—but it cannot hurt to have them released nonetheless.

■ Consider Side Letters

Where the Government will not agree to a broad release of entities or individuals, a settling company can always request a side or "cold comfort" letter. These letters announce that the Government has no present intention of taking additional enforcement action against the company, or its employees, and that its investigation is closed, barring new evidence of wrongdoing. Although side letters are not enforceable as a contract, and likely do not preclude future investigations, subpoenas, or claims,[37] they may provide some indication as to whether the Government is considering—or already investigating—additional claims. Even with no preclusive effect, cold comfort can be better than no comfort at all, especially for corporations and their employees that have labored through lengthy investigations.

Less Common Clauses

Most FCA settlement agreements contain the same core clauses, as discussed above, although the language and coverage is specific to each. But there are some less common clauses that occasionally pop up in settlement agreements. Some, such as detailing past cooperation, may be beneficial for a settling defendant. But others, such as requiring future cooperation or the unsealing of a *qui tam* complaint, appear to serve no useful purpose, and should be avoided.

■ Past Cooperation

One provision that settling parties may want to request, although it was rare in the settlements we reviewed, is a statement by the Government that the settling party cooperated with the Government's investigation and, if relevant, that there was no harm to the patients or program at issue. For example, when Christiana Care Health System (CCHS) settled an FCA case with the Government and the State of Delaware, the settlement agreement contained the following provision on cooperation and patient care:[38]

> The United States and the State of Delaware acknowledge that CCHS was cooperative during the investigation…and that the quality of patient care was neither compromised nor at issue in this investigation.

Although this clause is not common, and does not confer a legal right on the settling party, its language may soothe an organization or individual that is nervous that the fact of settlement will be interpreted by external parties as an implicit acknowledgement of wrongdoing. When the contract at issue concerns critical goods or services—such as patient treatment or military parts—this type of clause provides some cover that, even if a legal violation may have occurred, the practical consequences were nil.

■ Future Cooperation

A settlement agreement is often meant to resolve a pending Government investigation, to give the settling party finality that there is no longer a risk of litigation or FCA exposure. While the Government rarely provides express certainty that it is no longer investigating the company, it is often understood that a settlement will put the matter to rest. For that reason, few settlement agreements talk about a future investigation or the settling parties' cooperation in such an investigation. After all, why settle a claim if the Government is still looking for wrongdoing?

But, in a few instances, the Government has included a clause that required the settling party to cooperate in the Government's ongoing investigation. For example, AHS Hospital Corporation, Atlantic Health System, Inc., and Overlook Hospital (collectively, AHS) paid nearly $9 million to resolve allegations raised in a *qui tam* complaint that they provided inpatient hospital services for nonqualifying patients and improperly transferred patients to skilled nursing facilities. Despite the large payment, AHS agreed to cooperate in the Government's "continuing investigation into the matters alleged" and to encourage their officers, directors, and employees to do the same, including giving interviews and testimony:[39]

> AHS agrees to cooperate fully and truthfully with the United States in any continuing investigation into the matters alleged in the Civil Action, including matters not referred to in this Agreement as Covered Conduct. Upon reasonable notice, AHS shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals.

That AHS willingly agreed to this provision is surprising for two reasons. The first is that the provision signaled that the Government's investigation was not over, as it explicitly referenced a continuing investigation into the very same matters that were raised in the *qui tam* complaint. Unless the settling parties had some extraneous comfort that the investigation was in actuality over, this provision would be worrisome. The second is that the provision explicitly referenced an investigation into matters that were not covered by the parties' agreement, suggesting that the Government might later seek more settlement money for related allegations that did not fall under the agreement's scope. Since the purpose of a settlement agreement is to reduce risk and conclude a choppy chapter, this provision is best left to the editor's floor.

■ Unsealing The Qui Tam Complaint

A relator filing a *qui tam* complaint must first file it under seal, giving the Government an opportunity to investigate the allegations.[40] While the initial sealing period lasts 60 days, the Government almost always receives an extension, which means that FCA cases often stay under seal for months, if not years. During this time, the Government is free to interview witnesses and collect key documents, slowly building its case. Once the Government has completed its investigation, it may choose to settle the case without intervening or file a complaint in intervention, at which time the case is unsealed and open to public scrutiny. One strategy for settling a *qui tam* case, then, is to settle with the Government before it files a complaint in intervention, so that the complaint is never unsealed.

While settlement agreements are usually silent on whether the case will be unsealed, in at least one agreement the Government went out of its way to make clear that it would unseal the case following settlement: [41]

> The United States will intervene in and move to unseal the *Qui Tam* Action promptly upon execution of this Agreement.

If settling a *qui tam* case, there is no reason to include this provision where the agreement will end the litigation. Instead, a defendant should attempt to reach an agreement that is silent on whether the case will be unsealed or which preserves the seal altogether. The settlement agreement will itself become public; there is no need for a defendant to further agree to air its dirty laundry.

Don't Waste Your Breath (Provisions You Can't Negotiate)

Unlike the above provisions, there are numerous standard provisions in every settlement agreement that the Government will *not* negotiate. Many of these have been around for the past 20-plus years[42] and are likely not worth the trouble trying to negotiate. A few of the more notable provisions are discussed below.

■ Conduct/Claims Not Released

In addition to the broad categories of claims that the Government will negotiate and release, every FCA settlement also contains a laundry list of claims that the Government will *not* release. The following example from McKesson Corporation's $190 million FCA settlement is typical of the claims and liability that the Government will specifically reserve:[43]

> [T]he following claims of the United States are specifically reserved and are not released:

> a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
>
> b. Any criminal liability;
>
> c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
>
> d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
>
> e. Any liability based upon obligations created by this Agreement;
>
> f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
>
> g. Any liability for failure to deliver goods or services due; or
>
> h. Any liability for personal injury or property damage or for such other consequential damages arising from the Covered Conduct.

Many of these reservations are common sense—a civil settlement will not release criminal liability; an agreement will not release liability stemming from the obligations it creates; etc. And, for obvious reasons, conduct that is wholly unrelated to the covered conduct will not be released. Normally, there is no further reference to such other conduct in the settlement. Occasionally, however, where unrelated conduct may arguably relate to the covered conduct, it may be specifically excepted from the settlement, as in the following provision:[44]

> Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including [defendant] and Relator) are the following:...Any claims for the conduct alleged in UNDER SEAL v. UNDER SEAL, No. 10-362 (D. UT)[.]

Settling defendants should also be aware that they will not be released from any liability under the tax code or from liability related to defective products and services or a failure to deliver goods or services. In many instances, defendants will have no reason to be concerned with such continuing liability (it likely was not the source of their FCA problems in the first place), but they should be aware of such potential liability going forward.

■ Constitutional Waivers

One provision that may cause some defendants to initially do a double-take is a requirement that settling defendants waive their constitutional rights under the Fifth and Eighth Amendments to preclude further criminal or administrative remedies for the covered conduct. However, the following provision is found in virtually every FCA settlement:[45]

> [Defendant] waives and shall not assert any defenses [defendant] may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

Defendants may not be happy with such a waiver, but, as best we have seen, it is one of the pills a defendant may have to swallow in relieving itself of FCA liability.

■ Unallowable Costs

Similarly, the Government will insert into every FCA settlement agreement a standard provision that any costs incurred by a defendant relating to the covered conduct (e.g., investigating, correcting, settling, etc.) are expressly unallowable and may not be charged against the Government. The standard provision further requires the defendant to notify the Government of costs that had previously been submitted but would be unallowable given the terms of the settlement. The (lengthy) standard provision generally reads as follows:

> [Defendant] agrees to the following:
>
> a. <u>Unallowable Costs Defined:</u> that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of [defendant] . . . in connection with:
>
> (1) the matters covered by this Agreement;
>
> (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
>
> (3) [defendant's] investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil criminal investigation(s) in connection with

> the matters covered by this Agreement (including attorney's fees);
>
> (4) the negotiation and performance of this Agreement; [and]
>
> (5) the payment [defendant] makes to the United States pursuant to this Agreement, including costs and attorneys fees, are "Unallowable Costs" for government contracting purposes (hereinafter referred to as "Unallowable Costs"). The "matters covered by this Agreement" includes related criminal matters if any.
>
> b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by [defendant], and [defendant] shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States.
>
> c. Treatment of Unallowable Costs Previously Submitted for Payment: [Defendant] further agrees that within 90 days of the Effective Date of this Agreement it shall identify any unallowable costs (as defined in this Paragraph) included in payments previously sought by [defendant] or any of its subsidiaries or affiliates from the United States. [Defendant] agrees that the United States, at a minimum, shall be entitled to recoup from [defendant] any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs in any such payments. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by [defendant] or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by [defendant], or the effect of any such Unallowable Costs on the amount of such payments.
>
> d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine [defendant's] books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

In healthcare agreements or other settlements involving a Corporate Integrity Agreement (CIA), the standard provision may also identify as unallowable for Government contracting and healthcare program purposes any costs associated with "the negotiation of, and obligations undertaken pursuant to, the CIA to":[46]

> (i) retain an independent review organization to perform annual reviews as described …the CIA; and
>
> (ii) prepare and submit reports to the [Office of Inspector General of the Department of Health and Human Services]….
>
> However, nothing in this Paragraph…that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to [defendant].

Defendants should be aware of these provisions and their implications before entering into an FCA settlement. Depending on the extent of unallowable costs, the true cost of settlement may be greater than the defendant originally estimated, or it could be less, depending on the portion of the settlement payment, if not all of it, that is tax deductible.

■ Disclosure

Finally, any company negotiating an FCA settlement should be aware that the agreement *will* become public. The agreement will contain a provision similar, if not identical, to the following:[47]

> All parties consent to the disclosure of this Agreement, and information about this Agreement, to the public.

The DOJ will likely also issue a press release regarding the settlement.[48]

But, even though the agreement will become public, the settling defendant can attempt to negotiate the wording of any press release, or at least its timing. The Government may be reluctant to negotiate such matters, or claim that it lacks full control over them, but to the extent a defendant can determine when the agreement will be publicized, the defendant can prepare its own media relations strategy to address the settlement. Doing so may aid the settling defendant in minimizing the public relations message that can accompany any legal settlement.

Conclusion

The best FCA settlement agreement is the one a defendant never needs to write. Avoid FCA liability in the first place through effective compliance programs and employee training and life will be a lot easier. But, if a company does find itself negotiating an FCA settlement, it must carefully consider the language and provisions and keep in mind that it has the power to force negotiation. The more a company drives the negotiation and considers some of the above drafting tips (or, more importantly, avoids some of the aforementioned pitfalls), the more likely it will be able to live secure knowing that its troubles are fully and finally resolved.

GUIDELINES

These *Guidelines* are intended to assist you in understanding how FCA settlement agreements are negotiated. They are not, however, a substitute for professional representation in any specific situation.

1. *Be Detailed, But Not* Too *Detailed*: When crafting the definition of covered conduct, identify the allegations or conduct that you want the Government to release, being mindful not to exclude allegations or conduct that a copycat plaintiff could use against you.

2. *Cover Specific Contracts*: For Government contractors, it can be helpful to identify contracts, task orders, and delivery orders in the definition of covered conduct to ensure the agreement will release any and all allegations, conduct, or claims related to those contract vehicles.

3. *Get Your Timing Right*: Ensure the agreement releases liability for allegations or conduct as early as possible and up through the date of settlement; reject arbitrary dates that leave a foothold for copycat suits.

4. *Avoid Unhelpful Ambiguity*: Understand the desired scope of the release, and define the covered conduct without ambiguity that could later reduce that scope.

5. *Deny All Liability*: The settling defendant should admit to no FCA wrongdoing, even where there is a related criminal case.

6. *Coordinate With Other Settlements*: Consider the implications of—and the FCA settlement's effect on—other actual or potential criminal or administrative concerns.

7. *Release All Entities*: Consider corporate structure and organization and draft accordingly.

8. *Release Individuals*: Consider and release liability for relevant individuals, including former officers and employees.

9. *Protect Your Release*: Do not negate the release in the reservation of claims provision by, for example, excluding certain individuals or employees.

10. *Release Alternative Legal Theories*: Consider and release as many alternative legal theories as applicable, including common-law claims for unjust enrichment and payment by mistake.

11. *Consider Side Letters*: Cold comfort is better than no comfort. And merely asking for a side letter—and hearing the Government's response—may alert you to other investigations or *qui tam* cases.

12. *Past Cooperation*: Highlighting past cooperation can be beneficial but is rarely done.

13. *Future Cooperation*: Avoid committing to future cooperation in Government investigations, as the relevant investigation should be resolved by the settlement agreement.

14. *Unsealing the* Qui Tam *Complaint*: While *qui tam* complaints are often unsealed after settlement, this does not need to be a part of the agreement.

15. *Don't Waste Your Breath*: Negotiate where you can; understand where you cannot.

★ REFERENCES ★

1/ 31 U.S.C.A. §§ 3729 et seq.

2/ Elmer, "False Claims Act Settlement Agreements," 5 Crowell & Moring Business Crimes Update (Jan. 1994), http://www.crowell.com/Practices/White-Collar-Regulatory-Enforcement/articles/False-Claims-Act-Settlement-Agreements-Crowell-Moring-Business-Crimes-Update-Issue-No-5.

3/ DOJ Press Release No. 13-1352, "Justice Department Recovers $3.8 Billion From False Claims Act Cases in Fiscal Year 2013" (Dec. 20, 2013), http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html.

4/ Crowell & Moring LLP collects and maintains a database of FCA settlement agreements, a summary of which is available at http://www.crowell.com/files/False-Claims-Act-FCA-Settlements-Crowell-Moring.pdf. Citations throughout this paper identify FCA settlement agreements by the name of the settling defendant and date of settlement.

5/ See United States v. Bank of Am., 922 F. Supp. 2d 1 (D.D.C. 2013), appeal docketed, No. 13-5112 (D.C. Cir. Apr. 18, 2013).

6/ United States v. Bank of Am., 922 F. Supp. 2d 1 (D.D.C. 2013), appeal docketed, No. 13-5112 (D.C. Cir. Apr. 18, 2013).

7/ GlaxoSmithKline LLC settlement, July 2, 2012, available at http://www.justice.gov/opa/documents/gsk/off-label-agreement.pdf.

8/ False Claims Act Complaint and Demand for Jury Trial, U.S. ex rel. Garofolo v. FedEx Corp., Civ. No. 06-0815 (EGS).

9/ False Claims Act Complaint and Demand for Jury Trial, U.S. ex rel. Garofolo v. FedEx Corp., Civ. No. 06-0815 (EGS), para. 17.

10/ FedEx Corp. settlement, Apr. 29, 2011.

11/ Advance Pain Centers settlement, Mar. 9, 2010.

12/ Melbourne Internal Medicine Associates, P.A. settlement, Mar. 23, 2010.

13/ Educational Testing Service settlement, May 25, 2011, available at http://www.justice.gov/usao/nj/Press/files/pdffiles/2011/ETS%20Settlement%20Agreement.pdf.

14/ Hospice Family Care, Inc. settlement, May 31, 2012.

15/ DOJ Press Release, "TW Metals Settles False Claims Act Violations" (Mar. 19, 2008), available at http://www.justice.gov/usao/pae/News/2008/mar/twmetalsrelease.pdf.

16/ TW Metals, Inc. settlement, Mar. 19, 2008, available at http://www.justice.gov/usao/pae/News/2008/mar/twmetalssettlementagreement.pdf.

17/ 31 U.S.C.A. § 3731(b)(1). But see 31 U.S.C.A. § 3731(b)(2) (allowing FCA action to be brought within "3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed").

18/ FedEx Corp. settlement, Apr. 29, 2011.

19/ University of Phoenix settlement, Dec. 15, 2009.

20/ See United States ex rel. Carter v. Halliburton Co., 710 F.3d 171 (4th Cir. 2013), 55 GC ¶ 98 (holding Wartime Suspension of Limitations Act, 18 U.S.C.A. § 3287, suspends FCA statute of limitations).

21/ See United States v. Bank of Am., 922 F. Supp. 2d 1 (D.D.C. 2013), appeal docketed, No. 13-5112 (D.C. Cir. Apr. 18, 2013).

22/ Youth and Family Centered Services, Inc. settlement, Apr. 22, 2009, available at http://www.justice.gov/usao/pae/News/2009/apr/southwoodsettlementagreement.pdf.

23/ AstraZeneca LP settlement, Apr. 27, 2010, available at http://www.justice.gov/usao/pae/Pharma-Device/astrazeneca_settlementagreement.pdf.

24/ Cephalon Inc. settlement, Sept. 29, 2008, available at http://www.justice.gov/usao/pae/Pharma-Device/cephalon_settlementagreement.pdf; see also Ortho-McNeil Pharmaceutical, LLC settlement, Apr. 29, 2010 (same), available at http://www.justice.gov/usao/ma/news/2010/April/OrthoMcNeil/ortho.topamax.civil.sig.pdf.

25/ See, e.g., FAR 9.406-2(b)(1)(vi)(B) (debarment), 9.407-2(a)(8)(ii) (suspension).

26/ See, e.g., Exactech, Inc. settlement, Dec. 7, 2010, available at http://www.justice.gov/usao/nj/Press/files/pdffiles/2010/Exactech%20--%20Civil%20Settlement%20Agreement.pdf (releasing "Exactech, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; and affiliates; and the predecessors, successors and assigns of any of them"); GlaxoSmithKline LLC settlement, Oct. 26, 2010, available at http://www.justice.gov/usao/ma/news/2010/October/GSK%20Settlement%20Agreement10_26.pdf (releasing "GSK, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively").

27/ The Cooper Health System, Inc. settlement, Jan. 17, 2013, available at http://www.justice.gov/usao/nj/Press/files/pdffiles/2013/Cooper%20Health%20Settlement%20Agreement.pdf.

28/ Temple University settlement, May 15, 2012, available at http://www.justice.gov/usao/pae/News/2012/May/Temple%20Settlement%20Agreement.pdf.

29/ New York Machinery, LLC settlement, Dec. 17, 2010, available at http://www.justice.gov/usao/nj/Press/files/pdffiles/2010/New%20York%20Machinery%20Settlement%20Agreement.pdf.

30/ Christiana Health Care System settlement, Mar. 2, 2010, available at http://www.justice.gov/usao/de/news/2010/Final%20Signed%20settlement%20Agreement.pdf.

31/ Maxim Healthcare Services, Inc. settlement, Sept. 12, 2011, available at http://www.justice.gov/usao/nj/Press/files/pdffiles/2011/Maxim%20SA.pdf ("No individuals are released by this agreement."); St. Mary's Medical Center settlement, Dec. 28, 2010, available at http://www.justice.gov/usao/pae/News/2014/January/StMary_settlement2.pdf (same); Willowcrest Nursing Home settlement, Sept. 19, 2009, available at http://www.justice.gov/usao/pae/News/2009/aug/willowcrestwillowsettlementagreement.pdf (same); National Training and Information Center settlement, June 3, 2009, available at http://www.justice.gov/usao/iln/pr/chicago/2009/pr0603_01a.pdf (same); RBC Mortgage Co. settlement, Nov. 25, 2008, available at http://www.justice.gov/usao/iln/pr/chicago/2008/pr1125_01b.pdf (same).

32/ GlaxoSmithKline LLC settlement, July 2, 2012, available at http://www.justice.gov/opa/documents/gsk/plea-ex-b.pdf.

33/ GlaxoSmithKline LLC settlement, July 2, 2012, available at http://www.justice.gov/opa/documents/gsk/plea-ex-b.pdf.

34/ Novartis Pharmaceutical Corp. settlement, Sept. 30, 2010, available at http://www.justice.gov/usao/pae/Pharma-Device/novartis_settlementagreement.pdf; Cephalon Inc. settlement, Sept. 29, 2008, available at http://www.justice.gov/usao/pae/Pharma-Device/cephalon_settlementagreement.pdf.

35/ GlaxoSmithKline LLC settlement, July 2, 2012, available at http://www.justice.gov/opa/documents/gsk/off-label-agreement.pdf; see also Abbott Laboratories, Inc. settlement, May 7, 2012; Lenox Hill Hospital settlement, May 4, 2012; Beth Israel Medical Center settlement, Mar. 1, 2012; Merck & Co., Inc. settlement, Nov. 22, 2011; Garsh Lending LLC settlement, May 23, 2011.

36/ AstraZeneca LP settlement, Apr. 27, 2010, available at http://www.justice.gov/usao/pae/Pharma-Device/astrazeneca_settlementagreement.pdf.

37/ Fresenius Medical Care v. United States, 526 F.3d 372 (8th Cir. 2008).

38/ Christiana Care Health System settlement, Mar. 2, 2010, available at http://www.justice.gov/usao/de/news/2010/Final%20Signed%20settlement%20Agreement.pdf.

39/ AHS Hospital Corp. settlement, June 21, 2012, available at http://www.justice.gov/usao/nj/Press/files/pdffiles/2012/AHS%20Stipulation%20and%20Settlement.pdf.

40/ 31 U.S.C.A. § 3739(b)(2).

41/ Christiana Care Health System settlement, Mar. 2, 2010, available at http://www.justice.gov/usao/de/news/2010/Final%20Signed%20settlement%20Agreement.pdf.

42/ Elmer, "False Claims Act Settlement Agreements," 5 Crowell & Moring Business Crimes Update (Jan. 1994), http://www.crowell.com/Practices/White-Collar-Regulatory-Enforcement/articles/False-Claims-Act-Settlement-Agreements-Crowell-Moring-Business-Crimes-Update-Issue-No-5.

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45/ See, e.g., BlueCross BlueShield of Illinois settlement, Feb. 24, 2011, available at http://www.justice.gov/usao/iln/pr/chicago/2011/pr0224_01a.pdf.

46/ See, e.g., Amgen Inc. settlement, Dec. 19, 2012, available at http://www.justice.gov/iso/opa/resources/980201341619759798687.pdf.

47/ The Cooper Health System Inc. settlement, Jan. 17, 2013, available at http://www.justice.gov/usao/nj/Press/files/pdffiles/2013/Cooper%20Health%20Settlement%20Agreement.pdf.

48/ See, e.g., DOJ Press Release No. 13-1107, "Boston Scientific and Subsidiaries To Pay $30 Million for Guidant's Sale of Defective Heart Devices for Use in Medicare Patients" (Oct. 17, 2013), http://www.justice.gov/opa/pr/2013/October/13-civ-1107.html.