SETTLEMENT OF MAJOR HEALTHCARE FRAUD ENFORCEMENT PROCEEDINGS: A PROBING AND FRANK ANALYSIS OF THE COMPETING VARIABLES

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Introduction

In major healthcare fraud matters, parallel problems of shareholder suits, multi-district personal injury litigation, potential debarment proceedings, and individual liabilities all complicate the path to settlement. The determination of the U.S. Department of Justice ("DOJ") to use its criminal and civil enforcement powers in pursuit of fraud, backed by the investigative resources renewed again and again by Congress, promises a future caseload as full as the past, where more than $10 billion has been collected on the civil fraud side alone.[1]

The duration of investigative and litigation proceedings, the consumption of resources, and the sharp consequence for both sides of stark win-or-lose litigation cause the vast majority of these major fraud cases to be settled. While the alternative of litigating is high-risk, as well as painful and protracted, achieving settlement is no stroll down the primrose path. The negotiators must unwind complicated legal knots all along the way, convincing one another throughout the process of the validity of their substantive and financial positions. The list of issues to be addressed is long, and the interests of the many stakeholders on both sides often collide explosively.

This article presents a comprehensive review of the multi-faceted effort required to settle these complex cases, including the major building blocks for a settlement, as well as the collateral and residual consequences of a settlement on the parties, including the effect on future business operations. The article also provides practitioners confronting the negotiation of healthcare fraud enforcement settlements with a practical checklist of steps that form the path to a successful settlement.

Major Building Blocks of Settlement

Timing and the Decision Whether to Settle

Timing is a proxy for readiness. A determination of when to pursue settlement is often the product of many factors. Although business entities may value counsel's ability to obtain expeditious resolution of large legal matters that burden their cost centers and require repeated public disclosure, pursuing a settlement quickly rarely results in a successful resolution of a healthcare fraud case. In this arena, haste is usually ill-advised.

First, the Legal Merits

For the business entity, speed-to-resolution alone may be a short-sighted priority depending on the legal issues a case presents. Those issues are usually not discernible without reading and analyzing a formal complaint. Because more than three-quarters of major healthcare fraud cases are filed under seal pursuant to the *qui tam* provisions of the federal False Claims Act ("FCA" or "False Claims Act"),[2] it is unusual to have a copy of the complaint early in the investigation phase. The FCA permits the United States to carry on an investigation of the case for a period of sixty days – which is commonly extended on an *ex parte* basis for long periods by the U.S. District Court.[3] After favorably acting on one or more requests for extensions, some courts have refused DOJ requests for further extensions. Accordingly, it is not uncommon for a complaint to be unsealed and become public over DOJ objection.[4] During the sealed period, the defendant under investigation enjoys a modicum of privacy, but also does not have the benefit of standing before the court or the ability to formally challenge the lawsuit.

If a business entity has been the recipient of a DOJ or other agency subpoena during the sealed period, it becomes acutely aware that an investigation is proceeding and may quickly realize it is expending large sums for legal fees during this important investigative period. Even in a booming economy, an entity may understandably seek to limit investigation-related expenditures. This business objective, sometimes fueled by some managers' experience with various forms of private civil litigation, frequently leads to instructions from a client to their outside counsel to explore settlement.

Initiating early settlement discussions without having the sealed complaint in hand and understanding the full scope of the investigation may be a foolhardy exercise. Indeed, the unsealing of the complaint, whether with or without DOJ consent, reveals the relative strength of the legal claims. For example, in the now-commonplace cases that allege impermissible off-label marketing by pharmaceutical and medical device manufacturers as a predicate for alleged False Claims Act violations, the law is largely undeveloped, and the viability of legal claims has long been ripe for judicial examination

such as the long-awaited ruling by the Second Circuit Court of Appeals in *United States v. Caronia* on December 3, 2012.[5] Unsettled law, together with traditional defenses advanced in early motions to dismiss under Fed R. Civ. P. 12(b)(6) and 9(b), make the eventual possibility of outright *dismissal with prejudice* very real. As a result, the benefits of litigating for some period to seek dismissal of a False Claims Act case must be presented to the business defendant as a potentially cost-effective path to disposition. Of course, litigating can also lead to the development of the law beneficial to defendants.[6]

Arguably the DOJ would prefer to settle cases without putting its legal theories to the test in a binding, widely reported fashion. Prosecutors are typically not eager to run the risk of creating case law that could complicate their ability to pursue prosecution of major cases in the future. When motions to dismiss are brought in a *qui tam* case, the DOJ invests in the litigation of the legal issues with national scope and priorities in mind. The stakes are significant for both sides, to be sure, but less so if the defendant loses. The case merely proceeds then as it would have before with further discovery, motions, requests for summary judgment and potential settlement. If the defendant prevails, however, the case is likely headed for appeal on the pure legal issues alone. When a dismissal is sustained on appeal, the ability of future relators – or the government – to proceed on the challenged legal theories may be impeded, if not blocked. In addition, an appellate court opinion addressing off-label promotion, or whatever the core substantive legal issues happen to be, may outline the scope of "legitimate" business and marketing practices. The business interest in greater judicial clarity for daily healthcare operations is undeniably valuable.

These principles apply to additional areas to which the False Claims Act might apply, such as the tracking and filing of Medicaid claims and filing of student financial aid requests or even claims relating to government construction projects.[7] Other legal grounds for dismissal are rooted in the jurisdictional bars of the False Claims Act, which have been the subject of recent relator-friendly amendments.[8] Caution must be exercised to determine whether the amendments are applicable to a particular case. Dismissals on jurisdictional grounds are every bit as binding on the relator as dismissals on the merits. One advantage of pursuing dismissal on jurisdictional grounds is that the government may be deterred from intervening.[9]

In short, because the False Claims Act is a statute dense with text, the opportunity for legal challenge to a plaintiff's claim (whether the government or a relator) is often available for those who are skilled in parsing and litigating the statute.

Second, the Likelihood of Exposure

When considering the timing of settlement, an organization's exposure to liability on the merits is critical. A determination of the potential liability and the inevitable questions of fact that determine liability – unlike a challenge based on a flawed legal theory – is rarely if ever addressed in early motion practice. Dismissal motions on merits-related grounds are likely to be met by a response that post-discovery summary judgment is the proper time for hearing. In the case where the complaint has been unsealed and discovery not yet commenced, any post-discovery determination of liability on the merits may not occur until several years into the future.

Even though it is time-consuming, a thorough understanding of the strength of the theories of liability posed in each case is critical to both sides' assessments of whether settlement is appropriate. Because detailed assessment of the facts is necessary to assess potential exposure, the time and money needed to conduct a frank assessment of exposure on the merits may be frustrating to the managers of the business entity who have to fund legal fees and related expenses. Fact-finding in a major healthcare fraud enforcement matter is an involved undertaking by both sides. For the DOJ, the exercise of the sovereign's power to compel the production of documents – under grand jury authority, the Inspector General Act, and the False Claims Act[10] – along with its investigative powers to obtain testimony under oath both before the grand jury and in investigative depositions pursuant to civil investigative demands,[11] can be time consuming and detailed exercises, taking up to half a decade in many cases.[12]

For the defending entity and individuals, their internal investigation typically runs simultaneously with their response to DOJ inquiries. Unlike the DOJ, they do not have access to compulsory process for collecting documents from third parties or interviewing witnesses who might be highly useful to a liability assessment. For them, access to third-party information through compulsory process can occur only when formal discovery commences. Of course, third parties may be willing to provide some information on a voluntary basis without compulsory process, but there is no predictability or assurance that the desired information may be obtained.

Individuals and managers of entities involved in healthcare fraud enforcement investigations frequently ask counsel how to move the process more rapidly to resolution. The answer is typically viewed as unsatisfactory and this reality highlights the fundamental difference between government enforcement cases and private-party commercial litigation. The commencement of a criminal or civil case is an august exercise of the government's authority. Prosecutors bear the responsibility not to act on partial or unsubstantiated information. For law enforcement professionals, the prospect of missing evidence that results in the failure to charge an offense or failure to identify a defendant is simply not an acceptable risk. Indeed, premature action could expose DOJ attorneys – indeed whole United States Attorneys' offices – to unpleasant oversight problems of their own from supervisors, courts, Congress, the media, and the general public.

When dialogue commences very early in an investigation, DOJ attorneys must also determine whether they are being provided with biased information, or "being sold a bill of goods." The antidote to this risk is time-tested and proven: taking the steps and time to ensure that the facts underlying the DOJ case are solid and corroborated. Representations of facts by relators or their attorneys provide mere starting points. The *sine qua non*, as spoken by DOJ lawyers, is a full picture of the relevant facts delivered by trustworthy defense counsel.

The diligence with which the government is obligated to act does not mean that the defending entity or individuals are trapped in limbo until the investigation is completed. DOJ and defense investigations typically run in parallel, with both sides actively gathering facts and assessing liability to prepare for the moment when issues can be fully identified and debated.

When the timing is right, the secret ingredient for success is skilled information-sharing between the DOJ and defense negotiating teams and the injection of advocacy at every opportunity. The defending business entity and involved individuals know their documents, their business practices, and their people better than the DOJ ever can. Correspondingly, DOJ attempts to use whistleblowers and other insiders to help it understand the evidence and solicits views from assisting government agencies such as the Food and Drug Administration ("FDA"). A trusting but measured exchange provides the mutual benefit of knowing which facts are forming the views of both sides. To the uninitiated or unseasoned defense negotiator, there is a risk that it becomes a one-sided exercise, giving and giving and giving, without knowing that a fair two-way flow of information is achievable if the right approaches are used and the right level of trust is established.[13]

These highly structured information exchanges are often referred to by practitioners as "trial in the conference room," where skilled prosecutors and defense lawyers are in reality testing their cases. When the thoughtful exchange of carefully developed evidence is coupled with advocacy grounded in enforcement precedent as well as the law, it is not unheard of that the net result of the discussions would be a non-prosecution decision. Ironically, because these declinations – victories that are the product of intense work by the defense and realistic assessments by the government – are not papered or published, these results are not as visible to the profession as are the large settlements, criminal pleas, and punitive collateral components such as Corporate Integrity Agreements. Nonetheless, declinations do indeed happen. They are often the product of thoughtful analysis on both sides. Declinations are proof of the oft-repeated DOJ mantra that the DOJ wants to know the evidence so it can make a decision that is just and in the public interest.

Third, Extenuating Circumstances

The timing for commencement of negotiations may have nothing to do with the desire to effect a settlement. Just as the defending organization or individuals might decide that they would rather challenge the legal claims in court on the merits or on jurisdictional grounds, the DOJ might decide – either before a settlement overture or even during negotiations – that it would rather not settle the case. DOJ priorities such as deterrence, proportionality to other cases from across the country, or special facts it views to be egregious may cause it to reject the prospect of settlement and test its theory at trial. Under these circumstances, individuals who face the prospect of going to trial along with other defendants may succumb to pressure to become government witnesses and therefore work out plea bargains ahead of trial. When this flight to perceived safety with DOJ begins, every individual may be affected, with each wondering if he or she too should cut his or her losses and "flip," as the saying goes.

If settlement efforts fail the first time, they may succeed at some later stage, perhaps when DOJ attorneys determine whether the grand jury testimony they have procured aligns more closely with the defense's theories and arguments. Other drivers can include the impact on the defense of the revelation of third-party evidence about which the defense had not previously known, or outside events completely unrelated to the case. Some examples of influential external events include a change in corporate control or other transaction. Sometimes it may take several rounds of negotiations – separated by years – to achieve an eventual settlement.[14] Once settlement in principle is achieved, however, a collection of multi-agency approvals may be necessary for a global settlement, and the preparation of various settlement documents can take additional months.

Civil and Criminal Interplay: Entities and Individuals

The simultaneous pursuit of criminal and civil theories by the government presents complications for potential defendants. These complications are exacerbated when both an entity and individuals are subjects of the same government investigation. The interests of these parties are quite distinct, with both viewing the potential for a criminal conviction as the most threatening factor. For this reason, it is imperative that parties committed to settlement strive to achieve a global (and final) resolution.

For the DOJ, the ideal global conclusion usually consists of a corporate guilty plea and criminal fine, a civil settlement requiring payment of an amount that is tantamount to a hefty civil fraud penalty, some form of continuing oversight, and individual criminal convictions of high level persons.[15] In contrast, the ideal resolution for the defense consists of a declination of criminal prosecution for both entities and individuals and a dismissal on the merits of all civil fraud claims. Short of undeniable complete victory, a palatable outcome for the defense might be a criminal declination, a civil settlement by the entity with no admission of liability, a reasonable compromise payment and no form of ongoing government oversight. In this era of intense enforcement in the healthcare industry, all of these and everything in between has occurred.

Criminal versus Civil

To understand the crux of the debate over criminal versus civil liability, it is necessary to focus on the concept of intent, both for the involved organization and individuals. Case resolution ultimately will turn on whether skilled advocates can prevail on their respective arguments over the presence or absence of evidence of criminal intent. A thorough knowledge of the evidence is crucial to wage war over intent. Inflammatory emails, a top-level corporate marketing plan with alarming content, or the plea-bargained narrative of a former insider may carry the case. Each could be cited by the government as a "smoking gun" that establishes requisite intent. In response, countervailing evidence such as an organization's compliance efforts or other expressions of lawful intent may be advanced by the subjects of the investigation to negate, if not extinguish, the "smoking guns."

Discussions about evidence of intent, as well as arguments over the potential admissibility of evidence, are the stuff of the "conference room trial." This testing of the case constitutes the initial core of settlement negotiation. Indeed, the outcome of these discussions may be conveyed back to decision-makers on both sides and influence the future course of an investigation. The calculus for both sides involves questions such as "How strong is this evidence?" "Is the evidence admissible?" and "How will it play out before a jury?"

The threshold for corporate criminal liability is arguably a low one, based on a tort-like agency theory well-established since 1909 in *New York Central & Hudson River Railroad Company v. United*

States.[16] Under established law, if a corporate employee does an act for the benefit of the corporation that is within the scope of employment, the conduct is attributable to the corporation even if that action is criminal. It matters not that the corporation has policies and rules designed to prevent the commission of crimes by employees or has not expressly authorized the criminal behavior.

Nonetheless, the long-recognized ease with which a corporation may be convicted of criminal conduct is not the sole framework under which negotiations regarding potential entity culpability take place. The modern-day charging decision for corporate criminal liability is measured under the criteria of the DOJ, set forth in the McNulty,[17] Thompson,[18] and Holder Memoranda.[19] The nine criteria include: the nature and seriousness of the offense; how pervasive and how high the conduct goes in the corporation; whether there is recidivism; voluntary disclosure and cooperation by the corporation; adequacy of the compliance function at the company; corrective action taken by the corporation; collateral consequences of corporate prosecution on shareholders, employees, and the public; availability of prosecution of inside individuals; and adequacy of non-criminal remedies. Line-by-line consideration of each criterion in the Memoranda forms a fairly uniform agenda throughout the country for the discussion of potential corporate criminal responsibility with federal prosecutors.

In addition, many equitable considerations influence the negotiations. For example, the entity-annihilating prosecution of Arthur Andersen in the aftermath of the Enron scandal provides a justifiable basis for pause when the indictment of an entity is considered. The conviction of Arthur Andersen took an immeasurable toll on innocent officers and employees, eradicating jobs as well as retirees' benefits.[20] In light of this unfortunate experience, it is often possible to negotiate alternative resolutions to prevent massive job losses, anticompetitive consequences and harm to consumers who rely on products or services furnished by the corporate entity.

Indeed, the Deferred Prosecution Agreement ("DPA") and other forms of pre-trial diversion are viewed as measures that prevent catastrophic harm to innocent stakeholders. The DPA has become a tool of the prosecution to reform corporate conduct under the threat of indictment if compliance obligations go unfulfilled.[21] Similar vehicles, such as Corrective Action Plans or civil Consent Decrees under administrative agency oversight are less common, but equally viable solutions, especially in major healthcare matters.[22]

By statute, the Department of Health and Human Services' Office of Inspector General ("OIG") is required to mandatorily exclude healthcare entities convicted of a crime connected to the delivery of healthcare services.[23] Discretionary or so-called "permissive" OIG exclusion, as defined by the statute, can occur in other cases.[24] Negotiations of a criminal plea often turn on which component entity of a corporation could viably plead guilty to criminal charges, without causing an exclusion, also known as the "death penalty," to fall on the entity engaged in ongoing operations.[25] This solution, however, has provoked judicial scrutiny, and thus care must be taken to avoid rejection of the plea agreement by the court.[26] For this reason and others – such as the presentation of "agreed disposition" pleas under Fed. R. Crim. P. 11(c)(1)(c) – during negotiations directed at the potential for criminal charges, both sides must maintain awareness of the ultimate role the United States District Court in approving any corporate plea agreement.[27]

Entity versus Individual

Any negotiation over a potential corporate criminal disposition is hopelessly enmeshed with considerations about individual criminal accountability. Serious ethical principles apply to these considerations, where potential adverse interests converge for the defendants. The inter-relationship of individuals' fates with that of the entity creates a cascade where a decision on how to proceed with one may determine what happens to the others. For example, if the government persuades an individual to enter a guilty plea with a condition of cooperation against higher level individuals and the corporation prior to the initiation of any negotiations on a global resolution, the case is more likely to be resolved in pieces than globally.[28]

These scenarios are not only difficult for the defense side of the table, but also for the prosecution. As the recent failed prosecution of Stryker Biotech LLC in the U.S. District Court of Massachusetts illustrates, securing guilty pleas from individuals may create an illusion of prosecutorial strength and influence the government's willingness to settle with an entity with which the individuals were affiliated. Plea agreements may create the appearance of strength that masks other flaws in the government's theories. If the corporation has strong substantive legal arguments or powerful exculpatory evidence, the corporation may elect to go to trial in the criminal case to litigate that position. By the same token, the relative gravity of the first guilty plea can set off a chain of pleas, increasing the risk calculus for the corporation and its executives. Of course, a parade of pleas can also strengthen the remaining joint defense group's resolve to attempt to defeat the government. In other instances, the admission of guilt by one or more individuals and the evaluation of the evidence one or more cooperators can provide may quickly stimulate the desire for the negotiation of a global resolution by the remaining parties.

The power of the cascading pleas has shown itself in a newly developing area, that of the Responsible Corporate Officer doctrine.[29] In cases in which the doctrine is applicable, a corporate guilty plea may trigger government interest in the prosecution of a high-level executive. Under the Responsible Corporate Officer doctrine, an executive may be prosecuted simply for failure to exercise responsibility for the oversight of conduct subject to regulation. Liability under the doctrine – which does not require proof of criminal intent – has become stark in the last several years, with "strict liability" for such executives being affirmed by the courts.[30]

The importance of individuals to the ultimate fate of the entity militates in favor of a coordinated and cooperative defense. One way to achieve this goal is to invoke the benefits of the common interest privilege by having the lawyers for similarly situated subjects of the investigation execute a Joint Defense or "Common Interest" Agreement. The Agreement prescribes the conditions that will allow the protected exchange of information among lawyers without breaching the attorney-client privilege or attorney work-product doctrine.[31] This device allows multiple parties to evaluate the evidence supporting defenses, as well as exchange arguments to refute evidence that may be used by the government.

Financial Computation and Negotiation

Superficially, the dollar amounts for settlement – both criminal and civil – may appear formulaic, with the criminal component prescribed by the U.S. Sentencing Guidelines[32] and the civil component constructed by applying civil penalty and damages provisions of the FCA or other relevant statute.[33] The U.S. Supreme Court has determined that the Sentencing Guidelines are not binding on the sentencing court and while they may be considered, they are only advisory.[34]

The application of both the fine calculations under the Sentencing Guidelines and the False Claims Act can generate stratospheric sums for any sizeable corporate entity doing repeat business in a certain product or service line. By way of example, the vast majority of the $9 billion collected through civil enforcement actions in healthcare-related False Claims Act cases from January 2009 through September 2012 has come in relatively few settlements that exceed $100 million. In 2012 alone, top healthcare recoveries include $1.5 billion from GlaxoSmithKline and $441 million from Merck. A $561 million False Claims Act settlement with Abbott Laboratories, part of a $1.5 billion global resolution, was finalized in 2012, but will be included in recoveries for Fiscal Year 2013. The same holds true for criminal fines collected by the DOJ in healthcare cases.[35] Beneath the surface, and in the real world of the negotiation, there is a wide zone for debating the amount to be paid on both the criminal and civil sides.

Criminal

On the criminal side, the logical starting point is the itemized criteria of the Sentencing Guidelines themselves to determine the calculation of the fine. On virtually all criteria, there is legitimate room for varying opinions of how each factor should be determined. The accumulation of these differences on the criteria can add up to a significant swing in the total sum of corporate criminal fines. For example, the amount of gain or loss caused may be the subject of debate. How does one measure the unlawful "gain" that was reaped by a defendant entering a plea? What time period applies? Will there be any set-offs? Negotiations over these questions can have a material effect on the fine amount calculated under the Sentencing Guidelines.[36]

Moreover, the Sentencing Guidelines are only advisory. This status encourages advocacy on multiple grounds to alter the Guidelines calculation. For instance, the effort expended on systemic compliance efforts may hold some sway as an equitable factor. For health organizations with an inability to pay the amounts calculable under the Sentencing Guidelines, statutory provisions allow for relief.[37]

It is undeniable that the multiplier effect of repetitive transactions is the most decisive factor in arriving at the Sentencing Guidelines calculation, and in reaching the shockingly high sums seen in criminal healthcare settlements. The number of times a medicine or device is sold or a service is provided can drive the sum. The opportunity to negotiate mitigation is the province of the skilled negotiator. Efforts to isolate the appropriately narrow relevant transactions and correlate to the offense chosen can lead to a markedly different result from when one uses the universe as the base. Likewise, efforts to isolate the transaction base to the business segment or unit in which the conduct arose, or to the customer or customers involved rather than a universe of all customers, can serve the same end.

For individuals, the Sentencing Guidelines also must be considered as the structural starting point for determining any period of incarceration as well as any criminal fine. In the universe of corporate and individual criminal accountability that characterizes major healthcare fraud cases, it is important to be mindful that corporate indemnification for individual criminal fines is not allowed.[38] Indemnification similarly is not allowable for civil fraud judgments under the FCA, but these cases are less likely to involve individual liability.[39]

Civil

The False Claims Act provides a concrete framework for calculation of damages, often leading to astronomical sums for many of the same reasons as the Sentencing Guidelines. The analysis of the transaction base, and whether given transactions are properly isolated from the whole, can operate to mitigate the civil damages in the same way that it does for the criminal damages.

What is different, however, is the base concept for the damages to the United States for the false claims at issue in the case. This concept is a critical starting point for the negotiation of civil damages, which are conducted through the Civil Fraud chain of authority of the DOJ, rather than the Criminal Division. By way of example, in cases in which it is alleged that a hospital should have services in an observation setting, for which payment is made at an outpatient level rather than the higher inpatient setting, is the measure of damages under the False Claims Act the full value of the inpatient claim? Or is the measure of damages the full value of the inpatient reimbursement received by the hospital? But the patient received real and necessary services, so what about the difference between the inpatient reimbursement received and the outpatient reimbursement the hospital should have received? Each False Claims Act settlement is best served by a base analysis of damages customized to the type of healthcare service in issue. Negotiation over these customized analyses is critical to the calculation of a fair base amount. These methods of accurately assessing the financial damage to the government program in issue have been upheld in litigated False Claims Act cases.[40]

In an FCA case, it is also critical to obtain a concrete time frame for which the damages will be paid in the form of a settlement. The FCA has a six-year statute of limitations. The base amount of damages should not exceed the amount the DOJ could reach with a successful action under the statute. Some lesser period is typically sought by defendants. One consequence of the selection of a period for damages calculation is that this same period may be advanced by the DOJ as the appropriate period for which the United States is willing to give a comprehensive release.

Once the base damages formula has been negotiated, the number of transactions has been properly isolated, and the relevant period of time determined, there remain two additional quantitative aspects to calculation of the statutory civil fraud penalty to be paid as a settlement sum. First, the so-called "multiplier" must be determined; the FCA allows up to three times the damages to the government to be collected.[41] The differences between single, double, and treble damages in major healthcare fraud cases is immense and the negotiations commonly go into the decimal points between

1.0 and 2.0 and between 2.0 and 3.0. Sometimes, single damages plus an interest component is used as a proxy for a multiplier. The experience base of having negotiated multipliers, and the homework to assess the facts to be argued, are crucial to obtaining the best outcome – no matter whether the negotiator is a government or defense lawyer. The multiplier is elusive to all except those who have negotiated in these matters, as it is an unstated amount in published settlement documents.

The next remaining statutory damages task is to determine the civil penalties, if any, to be applied to each transaction. Again, the False Claims Act specifies a minimum of $5,500 and maximum of $11,000 for every false claim involved if a finding of liability is imposed after trial. Assuming the universe of these transactions has been properly analyzed, and a negotiated number of transactions is agreed upon, the amount of the per-claim penalty remains to be determined. This determination, as with the previously discussed multiplier determination, is a learned art in the world of False Claims Act negotiating. Indeed, in many situations, the presence of an ample recovery for the government elsewhere under the settlement results in no civil penalty amount.

If the base harm actually suffered by the government, the transaction universe of false claims, the multiplier, and the per-claim fine are not enough fodder for detailed negotiation, there are other civil damages remedies available to the DOJ. For example, the doctrine of disgorgement has been upheld as a legitimate remedy for false claims.[42] The equitable remedy of disgorgement looks not to what the loss has been to the plaintiff, but instead the wrongful gain by the defendant. The remedy is a creature of equity, while the related doctrine of forfeiture derives from statute. Forfeiture doctrine can also be applied, both civilly and criminally, and is typically sought in cases with highly egregious conduct. For instance, in the July 2012 GlaxoSmithKline settlement, a portion of the amount payable was characterized as a forfeiture. According to the DOJ Press Release, "[u]nder the terms of the plea agreement, [GlaxoSmithKline] will pay a total of $1 billion, including a criminal fine of $956,814,400 and forfeiture in the amount of $43,185,600…[GlaxoSmithKline] will also pay $2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states." Of course, the best shield against these all-encompassing remedies is a global resolution focused on the merits of the claim.

During the negotiation of criminal and civil healthcare fraud matters, the payable sums may be material to the corporate entity. If the corporation is a listed company, the sums being negotiated could at least theoretically, if not in reality, affect the company's stock price. Care must be taken with expert Securities and Exchange Commission ("SEC") counsel, on the one hand, to properly provide for confidentiality of demands and offers to protect against affecting the market through negotiations that may never consummate, and on the other hand, to timely and openly publish the settlement in accordance with SEC regulations. In addition, the protracted nature of negotiations over a global resolution may not align with disclosure obligations of a publicly traded entity. For that reason, an entity booking a large reserve to be used in a future settlement may have to make a public disclosure without knowing the full details about the settlement.

Nonmonetary Terms

The 2012 GlaxoSmithKline settlement agreement is replete with a variety of clauses, both boilerplate and non-boilerplate, that might be part of a major healthcare fraud enforcement negotiation.[43] Much of what might be regarded as boilerplate is DOJ policy, included for the sake of uniformity and fairness in disposition of cases across the nation. Understanding the consequences of these provisions is a must before the final agreement to a settlement, with several of them calling for special attention.

Unallowable Costs and Collections

The "unallowable costs" provisions of these settlement agreements cover large sums of money which may not be charged either directly or indirectly to government programs, such as Medicare. Included among the standard unallowable costs are the costs of defense for the investigation of the case, the costs of compliance with all of the collateral agreements to the settlement, including enhanced compliance programs and conditions, the corrective actions of the entity undertaken in response to the government investigation, and the amounts paid in settlement both to the federal government and the states.

In addition, the corporate defendant typically agrees not to seek payment for any of the healthcare products or services falling within the scope of the settlement, prohibiting collection of yet unreimbursed sums for those products or services. As a result, the settlement amount, coupled with this prohibition on seeking payment, covers both past and future collections of revenue for the covered conduct.

Tax Consequences

In civil healthcare fraud settlements, whether the settlement is negotiated under the False Claims Act or only common law theories of recovery, the United States always reserves all of its Title 26 (Income Tax Code) remedies, and expressly states that the settlement agreement terms cannot be construed as an agreement on any tax characterizations or consequences of the settlement amounts. For large-sum settlements, this provision is an important one, leaving the tax characterization risk solely up to the paying corporation. The deductibility of settlement-related costs is a unilateral decision that is made by the entity. Future Internal Revenue Service ("IRS") auditing is a reality, with virtually all significant healthcare fraud enforcement actions being the subject of audits for appropriate tax deductibility.[44]

When an IRS inquiry begins, it will be a virtual certainty that the IRS will request access to the demand and offer figures that were exchanged between the government and the defense, as well as any financial analyses of damages, fines, and penalties conducted by the parties. The subject of attorney-client privilege and work-product becomes a difficult one in this post-settlement timeframe, and the United States is known to provide its materials to the IRS. At a minimum, it can be expected that whatever spreadsheets or other form of exposure analysis has been provided to the United States by the defense, will in turn be given to the IRS, and in turn used by the IRS to test the deductibility decisions made by the corporation. Beyond that, there may well be a contest between the

IRS and the corporation about access to such litigation materials, where the extent of the privilege as well as work-product protection could be tested.

Scope of Releases and Covered Conduct Clauses

As mentioned above, the agreed-upon time-frame for the conduct covered by the settlement is a critical topic of negotiation affecting both the amount of the settlement sum and the scope of the release provided by the United States. Unlike private party litigation – where it is not unusual to exchange releases that run "from the beginning of the World to the present" – releases granted by the United States are carefully defined and limited in time. This creates an ironic reality: the more successfully the defense has narrowed the base of payment, the more future exposure there can be for additional enforcement, or additional relators to bring *qui tam* suits. For this reason, many experts deem it the most critical of the nonmonetary terms of the settlement. Accordingly, careful and thoughtful decisions must be made with all of this in mind, as an overarching concern in the settlement strategy. These considerations can make the "covered conduct" part of the negotiations particularly hard fought.

No Admission Clause

Defendants customarily insist on no admission of liability clauses in civil settlements with the United States. While often considered boilerplate in virtually all settlements, the dual criminal/civil nature of many healthcare fraud enforcement settlements creates complications in this area. To be valid, a plea agreement must include the entry of a guilty plea in open court, obviously requiring judicial admission of a series of facts and the essential elements of the crime. If a plea is required, the question arises of whether the inclusion of a no-admission clause in an accompanying civil settlement agreement is even possible.

Admissions of any fact or offense are never boilerplate. Should an entity become embroiled in another investigation conducted by the United States in the future, it is extremely important that the entity's history be devoid of as many admissions of violations of law as possible. A clean history without any admissions of violations of law is also important when the conduct of individuals affiliated with the settling entity is being evaluated by prosecutors. Furthermore, minimizing admissions deters follow-on litigation by third-party litigants who parlay the admissions into civil claims on behalf of individuals or organizations affected by the conduct. This parallel litigation phenomenon is of growing importance and has become a true force in creating seemingly unending litigation strings.[45]

The issues with no-admission clauses do not end there. The recent decision by United States District Judge Rakoff in a civil securities action, castigating the allowance of a no-admissions clause – in that case the SEC recital that facts are neither admitted nor denied – alongside a significant settlement, received both wide publicity and scholarly comment.[46]

This parcel of issues related to the once-common no-admission clause means that careful thinking and drafting must surround the handling of the topic in major healthcare fraud settlement agreements. When a civil agreement is executed in conjunction with a criminal plea, an effort must be made – perhaps by using different entities – to separate the admission necessary for a proper guilty plea from a civil agreement in which the signatory should always strive to make no admission of liability.

Press Releases

Both parties will retain their separate interests in crafting their own publicity about the settlement. It is typically not the practice of the DOJ to agree to a mutual press release or statement. The DOJ press release will be posted on its website, and DOJ leaders in Washington will most often be the spokespersons. It is not uncommon for the press statement to contain hyperbolic statements about the facts as well as superlatives about the size of the settlement and the gravity of the conduct addressed underlying the settlement.[47] In addition, the full settlement agreement and all of the corollary documents may be posted on the websites of the DOJ and OIG and will become part of the body of publicly available data about healthcare fraud enforcement settlements.

With this in mind, any press statement by the defense must be drafted to be consistent with the content of the settlement documents, because the statement will be scrutinized as a public statement of the company, and may itself, along with any statements made in a press interview, become fodder for those in search of parasitic claims.

The Role of the Relator

The relator, or whistleblower, is the person, usually an employee or former employee, who typically started the suit and consequential government investigation (although under the False Claims Act, the DOJ can initiate a suit without a relator). While the word "disgruntled" is often attached to the relator, the more neutral and accurate description is of a person who is impassioned about the importance of the case, usually because it is about his or her work area. Whether or not the DOJ decides to intervene in the relator's case,[48] he or she will be entitled to participate in the financial outcome of any settlement his or her complaint generates. The range of percentage share is statutorily dictated, and the actual sum is one negotiated between the relator and the DOJ.[49] Even if the DOJ has not intervened, the United States of America remains as the real party in interest for purposes of any settlement, because the damages are suffered by the United States, not the relator.[50] Therefore, any settlement agreement between the relator and the defense in the non-intervened case is subject to approval by the DOJ and the proceeds of a settlement belong to the United States, with shares as large as 35 percent plus attorney's fees awarded to the relator. The relator's share is a matter that is negotiated without any participation by the settling defendant. Attorney's fees, on the other hand, are negotiated directly between the relator and the settling defendant.

In a number of healthcare fraud investigations, there are outstanding claims by multiple relators. While the jurisdictional bar of "first to file" may eliminate all but the first of these relators depending on the timing of the case related to the FCA amendments,[51] there are numerous cases where the DOJ and the defense have agreed to settlement with multiple relators in an effort to globally resolve all disputes on a given subject.[52]

The relator has a separate right of recovery both under the non-

retaliation provisions of the FCA[53] and conventional non-retaliation and employment causes of actions under state law.[54] Compensation for the relator share of the governmental damages is not a recovery for the employment damages that may have been suffered by relator.[55] This area may become complex, and it is possible that the relator might not recover both forms of damages. For example, it may be determined that no employment-based claim is viable, and the relator receives only the fractional share of the governmental damages. Alternatively, if the relator negotiates an employment settlement with the corporate defendant and releases his right to obtain any other moneys, including a relator's share of *qui tam* proceeds, he may be barred by his release from that share of the settlement.[56]

Finally, a settling defendant in a False Claims Act case is required to pay the attorney's fees of a successful relator.[57] This amount, even in the intervened case, is typically not resolved as part of the settlement with the DOJ, and is, by agreement, left for negotiation between defense counsel and relator's counsel. If unresolved through negotiation, the amount to be paid is determined via fee petition to the court with jurisdiction over the *qui tam* case.

The Role of the States

Any filed major *qui tam* suit these days will have paragraph after paragraph naming the claims of the states from "A to Z". The large sums of money dispensed through the state Medicaid programs translate to proportionately significant amounts in any healthcare-related FCA case. Failure to include the states' interests in the settlement of such a case with the DOJ leaves very large exposure.

Typically, the states have standing Medicaid Fraud Units working with their respective Attorneys General; in many large cases, they work together across state lines through the National Association of Medicaid Fraud Control Units, or NAMFCU. NAMFCU provides a platform for the coordinated negotiation with states that elect to participate in the negotiations with the defendant through a chosen representative.[58] Although the substance of the negotiation is not different due to the addition of the Medicaid Fraud claims, failure to account for this aspect of the case during the settlement planning can add unwelcome surprise value to the settlement amount. It is also the case that some states fail to participate in the joint negotiations and leave at least a theoretical possibility of a tail settlement subsequent to the main settlement.

Ripple Effects on The Parties' Futures

Changes in Oversight

Even a short visit to the OIG's website will impress the viewer about the number of healthcare organizations that are operating under the restrictions imposed by a Corporate Integrity Agreement, commonly known as a "CIA."[59] Although the CIA is a near-omnipresent component of all major healthcare fraud settlements, this is beginning to change. The reasons are many, and not all self-evident. To understand the role of the CIA and why one may or may not appear in a settlement, it is helpful to examine the roots of the CIA phenomenon and its relationship to the DOJ settlement process.

The exclusion authority vested by statute and regulation in the OIG provides for the mandatory exclusion of persons and organizations that are convicted of certain healthcare-related offenses and permissive exclusion for healthcare-related civil and administrative transgressions. The OIG has responsibility over both mandatory and permissive exclusion proceedings.[60] Through agency coordination, the OIG is alerted about healthcare fraud investigations at the earliest stages, and often has a member of its staff as part of the investigative team. Similarly, a member of the OIG's legal counsel regularly participates in settlement negotiations, sitting at the table next to his or her DOJ colleagues. CIAs are negotiated by parties who wish to receive the express assurance that OIG will not institute any exclusion proceeding against the defendant or its employees.

CIA negotiation is typically conducted between counsel for the OIG and the defense after the terms of the settlement are reached with the DOJ. The process is often protracted and is as significant in its substance as the settlement of the criminal and civil claims. The impact of a CIA penetrates further into a healthcare organization than the civil settlement agreements or criminal fines and penalties, because it persists for years and affects daily business practices and regular employees. Moreover, the terms of a CIA may be applicable to every level of operations and governance, extending all the way up to oversight obligations of the board of directors. The requirements are typically sophisticated and tightly related to the exact form of business of the corporation that has signed the CIA. The required changes carry the potential to affect business results, and for example, can demand that covered persons find new ways to promote and sell their products. The execution of operational changes requires sophisticated project management, budgets, and personnel. Failure to train employees about their compliance obligations, establish monitoring and tracking systems for sales practices, self-report infractions, or certify oversight and compliance with the law can lead to specific liquidated penalties and truncated debarment proceedings where the company has agreed to waive many ordinary procedural and substantive rights by the terms of the CIA.

An examination of many of the major healthcare fraud enforcement CIAs demonstrates that the compliance requirements constitute deep changes in daily business practices, often nationwide. From time to time an outside monitor is appointed to sit with the board of directors and to oversee the compliance with the CIA, reporting findings directly to the OIG. The population of these CIAs and their cumulative consequences on the healthcare business can fairly be said to have created an entirely new super-governance expectation in the industry. More commonly, CIAs require the retention of an Independent Review Organization ("IRO") who will periodically conduct probing reviews – at the expense of the organization subject to the CIA – and report their findings to the OIG. Depending upon the scope and authority vested in the IRO through the CIA's terms, organizations can find this process to be expensive and disruptive.

The teeth behind the CIA are the liquidated penalties and the prospect of exclusion, both of which are within the control of the OIG. This is administrative and handled by the agency, outside the judicial system until and unless administrative appeals are involved. As such, it does not operate as a true probationary force with consequences enforceable in court by the DOJ when and if there is a violation. However, the DPA, mentioned above, has become the counterpart tool for the DOJ to achieve ongoing oversight into a defending company's business compliance. It is deployed as a

conditional criminal indictment, and held back from filing on the condition that the company complies with the negotiated oversight requirements. These often resemble those of the CIA, making breaches enforceable both as a matter of criminal process and administrative law. One of the more intrusive features of a DPA is the appointment of a monitor who supervises the operations of an organization much more closely and frequently than the sporadic auditing and monitoring conducted by IROs under a CIA.

In the July 2012 GlaxoSmithKline settlement a novel approach was taken to the criminal oversight arm of the agreement. Rather than enjoying the conditional benefit of DPA compliance, the company entered a guilty plea and agreed to an Addendum enforceable by the United States Attorney's Office in the United States District Court, requiring substantive compliance programs, including reporting of scientific data, sales compensation formula changes, abstention from marketing in independent medical education, and other items. The Addendum resembled in many respects the terms typically found in a DPA or a CIA.

Although there are public laments from time to time that corporations avoid true responsibility by treating healthcare misconduct as a mere fiscal cost of doing business, the deployment of the CIA, DPA, and plea agreement addendum demonstrate the real world of compliance change-making effectuated by settlement of these cases.

Parallel Proceedings and Third Party Litigation

Perhaps the most daunting aspect of major healthcare fraud enforcement actions is the multiplier effect on collateral or parallel proceedings. Certainly for legal counsel, the challenge is compounded exponentially. For both the government and defense counsel there are discovery challenges and demands from third parties and in far-flung courts, which demand ancillary preparations and appearances. More seriously, these actions may potentially upstage or disrupt the main healthcare enforcement case or settlement negotiation. It is not unheard of that something akin to a sophisticated organizational Gantt chart is necessary for keeping track of all the threads and their staggered time connections.

The discovery connections with the major healthcare enforcement case arise for the defense most often in the form of subpoena demands. For example, civil litigants in shareholder class actions or personal injury Multi-District Litigation ("MDL") proceedings are known to issue a subpoena for all documents produced to the government during the course of the government criminal or *qui tam* investigation. While the DOJ is not subject to subpoena of materials in its investigative phase due to the overriding need for confidentiality and secrecy of such proceedings,[61] there is no such investigative protection available to the defendant in third party proceedings. Instead, subpoena demands must be met with the ordinarily available avenues for quashing or limiting the breadth of subpoenas.[62] The MDL forum is particularly active, often involving aggregated proceedings that are piggybacked on medical device or pharmaceutical recalls, or enforcement actions related to off-label promotion.[63]

In the Merck MDL, Judge Fallon was required to rule on the intersection of civil proceedings and a government investigation when a report prepared by a Special Committee established by Merck's board of directors and related documents were sought in civil discovery. Generated through an investigation led by former federal judge John S. Martin, at the time a "Counsel" at Debevoise & Plimpton LLP, the "Martin Report" was the product of employee interviews, review of internal documents, consultation with experts, and communications with the Special Committee.[64] Merck's board publicly released the Report, which concluded that Merck's senior management acted appropriately in the development and marketing of Vioxx. When counsel for an MDL plaintiff and the Plaintiffs' Steering Committee served Merck with a request for production of documents related to the creation, preparation, and publication of the Martin Report, Merck filed a motion for a protective order, claiming that the materials were prepared in response to shareholder demands, existing and anticipated shareholder litigation, and pending regulatory investigations by the DOJ and SEC and therefore were protected from disclosure by the work-product and attorney-client privileges. Judge Fallon ruled that attorney work-product doctrine applied because the primary motivation of the investigation was to aid in possible future litigation. The Court reasoned that although the Report may have also been motivated by business purposes – such as creating positive media coverage – any potentially alternative motivation could not be considered in light of the prospective Vioxx litigation. Furthermore, the Court ruled that Merck had not waived the work-product doctrine through the publication of the Report, because Merck had never used the Report offensively in litigation.[65]

Plaintiffs' attorneys in parallel matters are known to cooperate with the DOJ by providing documents and witnesses in support of the government investigations. At times, through leaks to the press, key documents come to light in news stories, and in follow-on letters of Congressional inquiry. Senator Charles Grassley (R.-Iowa), invoking his oversight role as a member of the Senate Finance Committee and the Senate Judiciary Committee, is one of the frequent sources of these Congressional inquiries. For example, Senator Grassley issued highly publicized letters in June 2008 regarding his investigation of physicians at research universities nationwide. In letters published in the Congressional Record and broadly reported in the media, the Senator alleged that various doctors failed to report payments from drug and medical device companies, making bold assertions such as "[b]ased on reports from just a handful of drug companies, we know that even these millions do not account for all of the money."[66] When these events occur, the publication (without context) of supposedly significant documents often emboldens plaintiffs and the government, creating litigation management challenges for entities engaged in the ongoing defense of healthcare fraud enforcement proceedings or settlement negotiations.

It is important to remember that various parallel and collateral proceedings, whether they are settlements with a state attorney general, MDL settlements, shareholder class action settlements, or others will generate information that could influence the course of negotiating a global federal healthcare fraud settlement. Moreover, the announcement of settlements, or disclosure of reserves for possible settlement, can itself be the trigger for commencement of another parallel proceeding. For instance, according to public disclosures, the federal healthcare investigation of Merck commenced after the Vioxx MDL was disclosed. In addition, private healthcare insurers have observed the progress of government investigations and initiated their own actions, seeking huge recoveries on the

heels of a settlement involving government payors.

Whenever a significant healthcare fraud investigation surfaces, both government and defense counsel should anticipate the inevitable appearance of parallel civil actions and other proceedings. The parties should be prepared to deal with the consequences in their settlement strategy for the core enforcement action.

Conclusion

The economic and operational impact of settlements on participants in the healthcare industry mandates that attorneys practicing in the area to develop spcialized settlement skills to foster effective resolutions. A poorly negotiated settlement will exact tangible and intangible costs from an organization, and the bitter taste will linger for years. A well negotiated settlement can serve to eliminate or manage vast risk and allow an organization to maintain its focus on its core business, not legal matters.

The sea changes underway in the delivery and organization of the American healthcare economy will generate new regulatory schemes to govern daily business practice that will spur new enforcement activity under new theories. Most experts expect the scrutiny of the healthcare sector to increase, not diminish. As a result, confronted with the choice to litigate or settle, organizations will evaluate their options carefully and the demand for practitioners skilled in ways of effective negotiations will increase, as well. ■

A Practical Checklist For Practitioners

Because the peculiarities of each major healthcare fraud enforcement case range so widely and because the priorities of companies and individuals vary under their unique circumstances, there are no perfect templates or guidelines for achieving global resolution of these matters. Nevertheless, practical checklists can help define the scope of work that will be necessary before one embarks on settlement negotiations with federal law enforcement authorities.

1. Know Your Case Before You Start

- Facts Leading to Possible Liability
- Exculpatory or Mitigating Facts
- Potential Criminal, Civil and Administrative Proceedings
- Monetary Exposure
- Legal Issues
- Lineup of Parties

2. Be Conversant with Comparables

- Running Knowledge of DOJ Settlements
- Relevant Case Law Holdings
- What Can be Learned from Colleagues with Experience

3. Identify Decision Makers and Stakeholders

- Client
  - »Monetary Commitment (Limits on Authority to Settle)
  - »Business Side Clients
  - »Shareholder Interest
  - »Board of Directors
  - »Individual Defendants
  - »Individuals at Risk of becoming Defendants
- Federal Government
  - »Criminal Field Assistant U.S. Attorney (“AUSA”)
  - »Criminal DOJ Headquarters(“HQ”)
  - »Civil Field AUSA
  - »Civil Fraud Section HQ
  - »Agency (FDA, HHS, CMS)
  - »Comparable State Players
- Relator
  - »Individual Claims (Retaliation)
  - »Relator’s Share
  - »Multiple Relators
  - »Attorneys’ Fees
- Third Parties
  - »Third Party Insurers
  - »Shareholders
  - »Patients with Injuries
  - »IRS

4. Obtain Internal Consensus to Proceed

- Explain the Case to Decision Makers
- Explain Settlement Strategy

Endnotes

1 The current context of healthcare enforcement is well understood and covered in many easy-to-access locations. *See, e.g.*, How to Successfully Settle Major Health Care Enforcement Actions, July 12, 2012, http://apps.americanbar.org/cle/programs/t12hss1.html; Gibson, Dunn & Crutcher,2011Year-EndFalseClaimsActUpdate, http://www.gibsondunn.com/publications/pages/2011YearEndFalseClaimsActUpdate.aspx; U.S. Dep't of Justice, Fraud Statistics – Overview (Dec. 7, 2011), http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf; Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011(Dec. 19, 2011), http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html.

2 31 U.S.C. § 3729 *et seq*.

3 *See* 31 U.S.C. § 3730(b)(2).

4 *See, e.g.*, Sheri Qualters, Cases Deluge Boston Court, National Law Journal, Aug. 1, 2011 (describing how some District of Massachusetts judges have begun unsealing False Claims Act cases over government objections).

5 The off-label marketing example is an especially timely example for this concept of delaying settlement until a legal issue has been resolved. On December 3, 2012, the Second Circuit Court of Appeals issued an opinion reversing the criminalization of a pharmaceutical sales representative's oral off-label marketing. The decision in *United States v. Caronia*, 2012 WL 5992141 (2d Cir. Dec. 3, 2012), calls directly into question the underlying enforcement theory for the billions of dollars collected over the past decade in FCA off-label case settlements.

6 *See, e.g.*, *United States ex rel Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310 (D.Mass. 2011) (dismissing an off-label *qui tam* claim on legal grounds, holding that the relator's release of *qui tam* claims prior to filing his FCA action stripped him of standing, and that relator failed to allege fraud with particularity under Rule 9(b)); *United States ex rel. Bennett v. Medtronic, Inc.*, 747 F.Supp.2d 745 (S.D. Tex. 2010) (dismissing off-label case on the grounds that the relators' off-label promotion claims failed to state a claim under the FCA); United States ex rel. *Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004); *United States ex rel. Health Outcomes Tech.*, 409 F. Supp. 2d 43 (D. Mass. 2006); *United States ex rel. Cosens v. Baylor Univ. Med. Ctr.*, 469 F.3d 263 (2d Cir. 2006); *United States ex rel. Frazier v. IASIS Healthcare Corp.*, 554 F. Supp. 2d 966 (D. Ariz. 2008), *rev'd on other grounds*, 392 F. App'x 535 (9th Cir. 2011); *United States ex rel. Frazier v. IASIS Healthcare Corp.*, 812 F. Supp. 2d 1008 (D. Ariz. 2011).

7 *See United States ex rel. Digital Healthcare, Inc. v. Affiliated Computer Services, Inc.*, 778 F. Supp. 2d 37 (D.D.C. 2011) (dismissing on Rule 9(b) grounds relator's claim that defendant failed to take reasonable measures to determine whether Medicaid claimants had third-party insurance); *United States ex rel. Jajdelski v. Kaplan, Inc.*, 834 F. Supp. 2d 1182 (D. Nev. 2011) (dismissing relator's FCA claims alleging the filing of fraudulent financial aid requests under Rule 9(b)'s heightened pleading requirements).

8 *See* 31 U.S.C. § 3730(e)(4) (public disclosure bar).

9 *See, e.g., United States ex rel. Simpson v. Bayer Corp.*, 2012 WL 3600302 (D.N.J. Aug. 21, 2012) (vacating consolidation of multiple relators' cases based on first-to-file grounds); *United States ex rel. Poteet v. Medtronic*, 552 F.3d 503 (6th Cir. 2009) (affirming dismissal on public disclosure bar grounds).

10 *See* 31 U.S.C. § 3731(a); Fed. R. Crim. P. 6.

11 *See* 31 U.S.C. § 3733.

12 A simple comparison of public company Securities and Exchange Commission ("SEC") filing announcements of receipt of a subpoena, and the corresponding SEC announcement of settlement of that case, allows prediction of the length of such government investigations. For example, the GlaxoSmithKline settlement in July 2012 followed a nearly nine-year period of investigation. See Press Release, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), http://www.justice.gov/opa/pr/2012/July/12-civ-842.html.

13 It is critical to prepare binding agreements about how representations made during settlement may or may not be used in the eventuality of litigation and during any legal proceedings, in order to facilitate the free flow of information and prevent statements from being treated as admissions by a party.

14 *See supra note* 12.

15 *See* Press Release, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), http://www.justice.gov/opa/pr/2012/July/12-civ-842.html; Press Release, Justice Department Announces Largest Health Care Fraud Settlement in Its History (Sept. 2, 2009), http://www.justice.gov/opa/pr/2009/September/09-civ-900.html; Press Release, International Medical Device Maker Agrees to Plead Guilty in Connection with Shipments of Adulterated and Misbranded Bone Cement Products as Part of Unlawful Clinical Trials (Oct. 4, 2010), http://www.justice.gov/usao/pae/News/2010/Oct/synthes,norian_release.pdf.

16 212 U.S. 481 (1909).

17 http://www.justice.gov/dag/speeches/2006/mcnulty_memo.pdf.

18 http://www.justice.gov/dag/cftf/corporate_guidelines.htm.

19 http://www.justice.gov/criminal/fraud/documents/reports/1999/charging-corps.PDF.

20 See Greg Farrell, *Arthur Andersen Convicted of Obstruction of Justice*, USA Today, June 15, 2002, http://usatoday30.usatoday.com/money/energy/enron/andersen-verdict.htm; Kurt Eichenwald, *Andersen Guilty in Effort to Block Inquiry on Enron*, NY Times, June 16, 2002, http://www.nytimes.com/2002/06/16/business/andersen-guilty-in-effort-to-block-inquiry-on-enron.html?pagewanted=all&src=pm. That conviction was later unanimously overturned by the Supreme Court, *see Arthur Andersen LLP v. U.S.*, 544 U.S. 696 (2005), although it came too late to save the company. *See* Linda Greenhouse, *Justices Unanimously Overturn Conviction of Arthur Andersen*, NY Times, May 31, 2005, http://www.nytimes.com/2005/05/31/business/31wire-andersen.html?pagewanted=all (noting that "the decision represents little more than a Pyrrhic victory for Andersen, which lost its clients after being indicted on obstruction of justice charges and has no chance of returning as a viable enterprise").

21 As United States Attorney for the District of New Jersey, Chris Christie was especially active in this area. *See* Press Release, Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring (Sept. 27, 2007), http://www.justice.gov/usao/nj/Press/files/pdffiles/Older/hips0927.rel.pdf; Zimmer Deferred Prosecution Agreement, http://www.zimmer.com/web/enUS/pdf/Zimmer_DPA.pdf. Christie is now the Governor of New Jersey.

22 *See* Press Release, University of Minnesota Pays $32 Million to Settle Allegations of Selling an Unlicensed Drug and Mishandling NIH Grant Funds (Nov. 19, 1998), http://www.justice.gov/opa/pr/1998/November/549civ.htm; Press Release, Department of Justice Files Consent Decree of Permanent Injunction Against Ranbaxy (Jan. 25, 2012), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm289224.htm.

http://www.nytimes.com/2005/05/31/business/31wire-andersen.html?pagewanted=all (noting that "the decision represents little more than a Pyrrhic victory for Andersen, which lost its clients after being indicted on obstruction of justice charges and has no chance of returning as a viable enterprise").

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22 See Press Release, University of Minnesota Pays $32 Million to Settle Allegations of Selling an Unlicensed Drug and Mishandling NIH Grant Funds (Nov. 19, 1998), http://www.justice.gov/opa/pr/1998/November/549civ.htm; Press Release, Department of Justice Files Consent Decree of Permanent Injunction Against Ranbaxy (Jan. 25, 2012), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm289224.htm.

23 *See* 42 U.S.C. § 1320a-7(a).

24 *See* 42 U.S.C. § 1320a-7(b).

25 *See*, e.g., Press Release, International Medical Device Maker Agrees to Plead Guilty in Connection with Shipments of Adulterated and Misbranded Bone Cement Products (Oct. 4, 2010), http://www.fda.gov/ICECI/CriminalInvestigations/ucm228273.htm (noting that Norian, the subsidiary of Synthes, pled guilty to one felony and 110 misdemeanor counts, while Synthes pled to only one felony).

26 *See United States v. Guidant*, 708 F. Supp. 2d 903 (D. Minn. 2010).

27 *See* Jef Feeley & Janelle Lawrence, *Orthofix's Settlement of Medicare Probe Rejected by Judge*, Bloomberg Businessweek, Sept. 6, 2012, http://www.businessweek.com/news/2012-09-06/orthofix-s-settlement-of-medicare-probe-rejected-by-judge (reporting on United States District Judge Young's rejection of Orthofix's Rule 11(c)(1)(C) plea to obstructing a government audit and accompanying $7.8M fine).

28 The recent investigation into Stryker Biotech by the United States Attorney's Office for the District of Massachusetts provides a good example of this piecemeal resolution. *See* Eric Convey, E*x-Stryker Sales Rep. Pleads Guilty*, Boston Business Journal, Nov. 19, 2008, http://www.bizjournals.com/boston/stories/2008/11/17/daily36.html; Barry Meier, *Guilty Pleas in Inquiry Into Stryker's Marketing*, N.Y. Times, Feb. 20, 2009, at B4; Eric Convey, *Another ex-Stryker Biotech Rep. Pleads Guilty*, Boston Business Journal, Apr. 15, 2009, http://www.bizjournals.com/boston/stories/2009/04/13/daily25.html; Eric Convey, *Stryker Biotech Indicted on Several Grounds*, Boston Business Journal, Oct. 28, 2009, http://www.bizjournals.com/boston/stories/2009/10/26/daily37.html?page=all. Charges against the company and the individual defendants were eventually dismissed in the second week of trial. *See* Milton J. Valencia, *U.S. Dismisses Drug Salesmen's Case*, Boston Globe, Jan. 20, 2012, at 1.

29 *See* U*nited States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Park*, 421 U.S. 658 (1975).

30 S*ee United States v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) (accepting misdemeanor misbranding pleas of three high-level Purdue employees under the Responsible Corporate Officer doctrine); Jennifer Bragg et al., *Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine*, 65 Food & Drug L.J. 525 (2010); Brent Gurney et al. *The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA, Michael Friedman, et al. v. Kathleen Sebelius, et al.*, (No. 11-5028, D.C. Cir. 2012) (upholding HHS exclusions premised on misdemeanor convictions under the Responsible Corporate Officer doctrine.) http://www.wilmerhale.com/files/Publication/7b1c0866-a547-48c7-86d0-04d0449c03d7/Presentation/PublicationAttachment/c5eda281-2dae-4154-a0f8-13b817f25b52/The_Crime_of_Doing_Nothing.pdf.; David L. Douglass and Matthew M. Benov., *Healthcare Fraud Enforcement After Healthcare Reform (Or "More. More. More. How Do You Like It? How Do You Like It?")*, The Health Lawyer, Vol. 23, No. 6 (August 2011), at 35 (including a detailed discussion of the doctrine and recent developments); Robert T. Rhoad and Brian M. Castro, *Healthcare Executives in the Crosshairs: Navigating the Emerging Threat of Prosecution and Exclusion Under the Responsible Corporate Officer Doctrine*, The Health Lawyer, Vol. 24, No. 5 (June 2012).

31 The requirements for maintenance of privilege and ethical responsibilities under a Joint Defense Agreement are rigorous, and demand experience and tending during the life of a major healthcare enforcement action. The pitfalls are many, and bear potentially serious consequences. For example, in *United States v. Ruehle*, the Ninth Circuit held that a defendant's statements to his attorneys, who were representing another client at the time the statements were made, were not protected, in part because of a failure to give an *Upjohn* warning. 583 F.3d 600 (9th Cir. 2009).

32 *See* United States Sentencing Commission, Guidelines Manual, §8C, http://www.ussc.gov/guidelines/2012_Guidelines/Manual_PDF/Chapter_8.pdf.

33 *See* 31 U.S.C. § 3729(a) (imposing damages of not less than $5,000, plus three times the amount of damages which the government sustained because of the violation).

34 *United States v. Booker*, 543 U.S. 220 (2005).

35 *See* "Department of Justice Recovers $3 Billion in False Claims Cases in Fiscal Year 2010," *available* at http://www.justice.gov/opa/pr/2010/November/10-civ-1335.html (Nov. 22, 2010) ("In fiscal year 2010, those efforts [of the Civil Division's Office of Consumer Litigation ("OCL") which brings civil and criminal actions for violations of the Food, Drugs and Cosmetics Act ("FDCA")] yielded more than $1.8 billion in criminal fines, forfeitures, restitution and disgorgement, the largest healthcare-related amount under the FDCA in department history. Since January 2009, OCL has successfully pursued cases resulting in 25 criminal convictions and more than $3 billion in fines, forfeitures, restitution and disgorgement.")

36 The Guidelines also will produce differing results depending on the substantive crime, or crimes, chosen for the guilty plea. Obviously, lesser offenses will generate smaller numbers, and consequently, the negotiation must encompass what the ultimate substantive offense will be for entry of the plea.

37 See United States Sentencing Commission, Guidelines Manual, §8C3.3(b) (noting that the court may impose a fine below that other-wise required by §8C2.7 and §8C2.9 "if the court finds that the organization is not able and, even with the use of a reasonable install-ment schedule, is not likely to become able to pay the minimum fine required by §8C2.7").

38 A complex of judicial decisions, Delaware and other state corporate statutes, and corporate policies and bylaws govern the area of indemnification both for costs of defense and liability. *See, e.g.*, 8 Del. C. § 145(a) (providing for permissive indemnification if the person acted in good faith and in a manner reasonably believed to be in the corporation's best interests, and, with respect to criminal actions, if the person "had no reasonable cause to believe the person's conduct was unlawful"); *Hermelin v. K-V Pharmaceutical Co.*, 2012 WL 395826 (Del. Ch. Feb. 7, 2012) ("The Delaware General Corporation Law ("DGCL") sets two boundaries for indemnification: The statute requires a corporation to indemnify a person who was made a party to a proceeding by reason of his service to the corporation and has achieved success on the merits or otherwise in that proceeding. At the other

end of the spectrum, the statute prohibits a corporation from indemnifying a corporate official who was not successful in the underlying proceeding and has acted, essentially, in bad faith."); *Globus v. Law Research Serv., Inc.*, 418 F.2d 1276, 1288 (2d Cir. 1969) ("It is well established that one cannot insure himself against his own reck-less, willful or criminal misconduct.").

39 *See, e.g., Mortgages, Inc. v. U.S. District Court for the District of Nevada*, 934 F.2d 209 (9th Cir. 1990) (holding that counterclaims for indemnification are barred under the False Claims Act).

40 "Fraud comes in many varied forms and there is no set formula for calculating damages set forth in the FCA. Because each case under the FCA involves unique circumstances and types of damage to the government, the Court must devise a proper standard for measuring the damages directly caused to the government by the filing of a false claim. Damages have been measured by the courts in a variety of ways, and the method of measurement is influenced by the nature of the fraud and the type of government transaction affected by the fraud." *United States v. Estate of Rogers*, 2001 WL 818160, at *32 (E.D.Tenn. June 28, 2001) (citations omitted).

For example, a frequently recurring cause of action under the FCA is the fraudulent delivery of defective or nonconforming goods. In such cases, where the goods have been of sufficient value to be retained or used, courts have held that the measure of damages was the difference between the value of what the government received and the value of what it would have received had the fraud not occurred. *See id.* ("Ordinarily the proper measure of damages in a FCA case is the difference between what the government actually paid out by reason of the false claim over and above what it would have paid had the government known the true facts.") (citations omitted).

In those cases where, as a result of the defects or nonconformities, some or all of the goods were left unused, the courts have held that damages should be based on that percentage of the amounts paid by the government corresponding to the percentage of goods left unused because of the defects or nonconformities. *See United States v. Midwest Specialties, Inc.*, 1995 WL 811966, at *2 (N.D. Ohio Sep. 27, 1995) ("Generally, where the government has received a benefit despite the claim's falsity, the proper measure of damages is the market value of the goods minus their value as actually received. *See United States v. Bornstein*, 423 U.S. 303, 316 n. 13 (1976); *United States v. Board of Education of Union City*, 697 F. Supp. 167, 172 (D. N.J. 1988). For example, in *Henry v. United States*, 424 F.2d 677 (5th Cir. 1970), a government contractor delivered disinfectant that generally had insufficient pine oil amounts. The government used the disinfectant until testing revealed that it was 'without value for [the government's] purposes.' The court calculated damages as the contract price minus the 'value of that part of the merchandise which the government used.' *Id.* at 678. Similarly, in *Faulk v. United States*, 198 F.2d 169, 171 (5th Cir. 1952), where 15% of the milk delivered to the government did not conform to the contract, damages equaled 15% of the contract price.").

41 31 U.S.C. § 3729(a).

42 *See United States ex rel. Zissler v. Regents of Univ. of Minnesota*, 154 F.3d 870 (8th Cir. 1998).

43 *See* Settlement Agreement, http://www.justice.gov/opa/documents/gsk/off-label-agreement.pdf.

44 Generally speaking, criminal fines and civil penalties imposed to enforce the law are not deductible, while civil penalties imposed for other reasons may be. *See* 26 U.S.C. § 162(f) ("No deduction shall be allowed . . . for any fine or similar penalty paid to a government for the violation of any law."); 26 CFR 1.162-21 (same); *Comm'r of Internal Revenue v. Heininger*, 320 U.S. 467, 473 (1943) ("Where a taxpayer has violated a federal or a state statute and incurred a fine or penalty he has not been permitted a tax deduction for its payment."); *Southern Pacific Transp. Co. v. Comm'r*, 75 T.C. 497, 652 (1980) ("If a civil penalty is imposed for purposes of enforcing the law and as punishment for the violation thereof, its purpose is the same as a fine exacted under a criminal statute and it is 'similar' to a fine. However, if the civil penalty is imposed to encourage prompt compliance with a requirement of the law, or as a remedial measure to compensate another party for expenses incurred as a result of the violation, it does not serve the same purpose as a criminal fine and is not 'similar' to a fine within the meaning of section 162(f).").

45 For example, following Merck's November 2007 $4.85 billion settlement to resolve Vioxx-related claims (*see* www.browngreer.com/vioxxsettlement), numerous additional cases were filed against the company by various parties, including individuals, state Attorneys General, and federal authorities. As disclosed in Merck's 10-K Annual Report filed for the period ending December 31, 2008, *available at* http://www.merck.com/investors/financials/sec-filings, in 2008 various class actions were pending in U.S. courts purportedly brought on behalf of individual purchasers or users of Vioxx and claiming either reimbursement of alleged economic loss or an entitlement to medical monitoring. In June 2008, a Missouri state court certified a class of Missouri plaintiffs seeking reimbursement for out-of-pocket costs relating to Vioxx, and plaintiffs also filed a class action in California state court seeking class certification of California third-party payors and end-users.

Merck was also named as a defendant in 18 separate lawsuits brought by Attorneys General of ten states, five counties, the City of New York, and private citizens (who brought *qui tam* and taxpayer derivative suits), alleging Merck misrepresented the safety of Vioxx and seeking (1) recovery of the cost of Vioxx purchased or reimbursed by the state and its agencies; (2) reimbursement of all sums paid by the state and its agencies for medical services for the treatment of persons injured by Vioxx; (3) damages under various common law theories; and/or (4) remedies under various state statutory theories, including state consumer fraud and fair business practices or Medicaid fraud statutes, including civil penalties. Most of these actions were transferred to the federal multidistrict litigation ("MDL").

In addition, the SEC was conducting a formal investigation of Merck concerning Vioxx, and the DOJ had issued a subpoena requesting information relating to Merck's research, marketing, and selling activities with respect to Vioxx in a federal healthcare investigation under criminal statutes.

Suits were also filed in 2008 by two groups of various private insurance companies and health plans against BrownGreer, the claims administrator for the settlement program, and U.S. Bancorp, escrow agent for the settlement program, claiming to have paid healthcare costs on behalf of some of the enrolling claimants and seeking to enjoin the claims administrator from paying enrolled claimants until their claims for reimbursement from the enrolled claimants were resolved.

46 *SEC v. Citigroup Global Markets Inc.*, 827 F.Supp.2d 328 (S.D.N.Y. 2011).

47 *See* http://www.justice.gov/briefing-room.html.

48 *See* 31 U.S.C. § 3730(b)(2).

49 Relators are entitled to a 15% to 25% share of the settlement proceeds when the government proceeds with an action brought by the relators. *United*

States ex rel. Rille v. Cisco Systems, Inc., 2011 WL 4352309, at *2 (E.D. Ark. Sept. 19, 2011) (citing 31 U.S.C. § 3730(d)). The percentage that should be awarded within this range, however, depends on "the extent to which the [relator] substantially contributed to the prosecution of the action." *Id.*

The DOJ has developed guidelines setting forth the factors it considers in assessing a relator's share. Claire M. Sylvia, The False Claims Act: Fraud Against the Government § 8:13. According to the guidelines, in cases where the government intervenes, the analysis begins with 15%, which is essentially considered a "finder's fee." *Id.* The percentage may then increase based on several listed factors; for example, if the relator reported the fraud promptly, the complaint exposed a nationwide practice, or the relator provided extensive, first-hand details of the fraud to the government. *Id.* After determining the extent to which a higher award is justified, the guidelines suggest that a second set of criteria should be considered to determine whether the percentage should be reduced; for example, if the relator participated in the fraud, the relator's knowledge was based primarily on public information, or the government already knew of the fraud. *Id.*

50 "[T]he United States is the real party in interest in *qui tam* cases even where the government has not, or elects not, to intervene. This is so because … even when it does not intervene, the government receives the lion's share of any amount recovered and retains significant rights over the litigation." United States ex rel. *Doe v. X, Inc.*, 246 B.R. 817 (E.D. Va. 2000) (citing *Milam v. Univ. of Texas M.D. Anderson Cancer Ctr.*, 961 F.2d 46, 49 (4th Cir. 1992)).

51 *See, e.g.*, *United States ex rel. Simpson v. Bayer Corp.*, 2012 WL 3600302 (D.N.J. Aug. 21, 2012) (vacating consolidation of multiple relators' cases based on first-to-file grounds).

52 For example, in 2008 Cephalon entered a settlement with the government and four *qui tam* relators relating to Cephalon's off-label marketing of Gabitril, Actiq, and Provigil. See Press Release, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), http://www.justice.gov/opa/pr/2008/September/08-civ-860.html.

53 31 U.S.C. 3730(h)(2) (entitling relators who prove retaliation to reinstatement with seniority status, two times back pay with interest, compensation for any "special damages," and reasonable attorney's fees and costs).

54 *See, e.g.*, *United States ex rel. Scott v. Cancio*, 2011 WL 5975782, at *1 (M.D. Fla. Nov. 28, 2011) (noting that the plaintiff filed a separate employment action for discrimination and retaliation prior to filing his *qui tam* action).

55 *Compare* 31 U.S.C. § 3730(d)(1)-(d)(2) (authorizing the relator to receive up to 30% of the action or settlement of the claim), *with* 31 U.S.C. 3730(h)(2) (damages for retaliation).

56 *United States ex rel Nowak v. Medtronic*, 806 F. Supp. 2d 310 (D.Mass. 2011)

57 31 U.S.C. § 3730(d)(1)-(2).

58 *See* http://www.namfcu.net/.

59 *See* "Complete CIA List," *available* at https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp (listing 347 providers under CIAs, effective from 2002 to the present).

60 *See* 42 U.S.C. § 1320a-7. Mandatory exclusion from participation in any federal healthcare program applies to individuals and entities that have been convicted of: (1) program-related or (2) patient abuse-related criminal offenses in connection with the delivery of a healthcare item or service; (3) a felony related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a healthcare item or service or with respect to any act or omission in a healthcare program; or (4) a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Permissive exclusion allows the OIG to exclude individuals and entities from any federal healthcare program for: convictions relating to fraud or obstruction of an investigation or audit; a misdemeanor conviction relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance; revocation or suspension of the individual's or entity's healthcare license; exclusion or suspension under any federal or state healthcare program; submission of claims for excessive charges or unnecessary services, or the failure of certain organizations to furnish medically necessary services; engaging in fraud, kickbacks, and other prohibited activities; entities controlled by a sanctioned individual or individuals controlling a sanctioned entity; failure to disclose required information, supply requested information on subcontractors and suppliers, or supply payment information; failure to grant immediate access to the OIG or other enumerated regulatory body; failure to take a required corrective action; default on health education loan or scholarship obligations; and making a false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract.

61 *See* 28 C.F.R. § 16.26 (precluding disclosure when it "would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which would thereby be impaired").

62 *See, e.g., Minneapolis Firefighter's Relief, Ass'n v. Medtronic, Inc.,* 2011 WL 6957556 (D. Minn. Dec. 30, 2011) (granting motion to compel production of documents by defendant's witness, withheld under assertion of Fifth Amendment privilege).

63 S*ee, e.g., In re Vioxx Products Liab. Litig.*, MDL No. 1657 (multidistrict litigation resulting from the centralizing of 148 actions pending in 41 federal districts, all focused on alleged increased health risks when taking Vioxx, an anti-inflammatory drug, and whether defendant Merck knew of and failed to disclose these increased risks to the medical community and consumers); *In re Neurontin Mktg. and Sales Practices Litig.*, MDL No. 1629 (nationwide plaintiffs alleged that defendants Warner–Lambert and Pfizer, the manufacturers and distributors of Neurontin, systematically and knowingly engaged in a fraudulent campaign to market and sell Neurontin for treatment of "off-label" conditions for which defendants knew Neurontin was not effective).

64 *See* Report of The Honorable John S. Martin, Jr. to the Special Committee of the Board of Directors of Merck & Co., Inc. Concerning the Conduct of Senior Management in the Development and Marketing of Vioxx, http://online.wsj.com/public/resources/documents/merck-report-20060906.pdf.

65 *See* Order & Reasons, J. Fallon, Mar. 3, 2007, *In re Vioxx Products Liab. Litig.*, MDL No. 1657.

66 110 Cong. Rec. S5029 (daily ed. June 4, 2008) (letter of Sen. Grassley); *see also* 110 Cong. Rec. S5956 (daily ed. June 23, 2008) (letter of Sen. Grassley).