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The Judge Doth Reject: How to Prepare for Increased Judicial Scrutiny of Corporate Settlement Agreements in Health Care Cases [Ober|Kaler]

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Federal judges have historically accepted without much public commentary “global” settlements reached by government regulators and large corporations that resolve criminal and civil liability. In the past decade, judges have routinely approved settlements that have led to notable corporate compliance reform while simultaneously imposing significant fines and penalties against corporate defendants. Nuanced global settlements have been especially prevalent in the health care context, where defendant providers and suppliers seek to reach agreement with a host of government agencies in a manner that avoids some of the most drastic collateral consequences.

While in recent years the government and the defense bar have become accustomed to relatively little judicial objection to their proposed resolutions, the status quo is now in flux. Jurists like Judge Jed Rakoff of the U.S. District Court for the Southern District of New York have caught the attention of the legal community through their increased scrutiny of corporate settlement agreements. In two high-profile securities law cases involving Bank of America and Citigroup, Judge Rakoff criticized proposed settlements as being overly lenient and opaque.[1] Other judges have followed suit, creating a chorus of judicial disapproval for the Securities and Exchange Commission's policies, which have been viewed as misaligned with the public interest in the wake of the recent financial crisis.[2]

As revealed in current events, judges have begun to express concerns about the terms of global settlements in cases outside of the securities law context. Cases involving Orthofix International N.V. (“Orthofix”) and WakeMed Health and Hospitals (“WakeMed”) demonstrate how judges are beginning to conduct exacting reviews of corporate settlements in the health care arena. The precedent set in these cases potentially has enormous implications for defense counsel in major health care cases.

Orthofix

In June of 2012, medical device manufacturer Orthofix reached a global resolution with federal prosecutors under which the company agreed to: pay $34 million to resolve False Claims Act allegations, pay a $7.7 million criminal fine, and have one of its subsidiaries plead guilty to a felony obstruction offense. The False Claims Act case was initiated by a whistleblower who alleged that certain company sales reps had falsified certificates of medical necessity (CMN) when seeking Medicare reimbursement for several bone-growth stimulators. The criminal charge stemmed from Orthofix's alleged failure to disclose material information to the government during a Medicare audit of its practices related to the CMNs. As part of the settlement, Orthofix agreed to enter into a far-reaching Corporate Integrity Agreement (CIA) with the Department of Health and Human Services (HHS), Office of Inspector General (OIG). In related criminal resolutions, several now-former Orthofix employees and contractors pleaded guilty to felony convictions for their activities, which included the payment of physician kickbacks and the falsification of patient medical records.

Although both the government and Orthofix agreed that the settlement was reasonable, it failed to initially satisfy Judge William Young of the U.S District Court for the District of Massachusetts. Judge Young stated that the agreement lacked sufficient protection for the public interest and noted his “extreme unease of treating corporate criminal conduct like a civil case.”[3] In addition, he criticized the initial plea agreement as being made pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), which would have foreclosed the judge's ability to impose additional penalties—noting that in cases involving corporate misconduct of this scale, “the court's hands ought not to be tied.”[4]

After revising the terms of the agreement three times, Judge Young finally accepted the settlement in December of 2012. In addition to monetary penalties of over $40 million, Judge Young imposed a five-year term of probation, during which time Orthofix is required to comply with the terms of the previously-executed CIA. Finally, Judge Young inserted a special condition of probation under which Orthofix and its agents were forbidden from disavowing the factual basis for the guilty plea.[5]

WakeMed

WakeMed, a North Carolina based non-profit health care system, became a law enforcement target after a 2007 audit identified one of its hospitals as having an inflated number of “zero-day stay” billings, under which inpatient stays lasting less than a day were improperly billed to Medicare. The government subsequently alleged that the hospital's cardiac center had been improperly classifying patients for inpatient hospital stays—a practice that helped the hospital to receive approximately $1.2 million in overpayments between 2003 and 2010.

The hospital entered into global settlement negotiations that included a civil agreement to resolve False Claims Act charges, a two-year Deferred Prosecution Agreement (DPA), and a five-year Corporate Integrity Agreement (CIA). The hospital agreed to pay $8 million and to submit to a two-year probationary period under the DPA, during which time it would be subject to an independent auditor's review. The WakeMed case has been viewed as unique, for while it not uncommon for health care providers to face civil False Claims Act charges for upcoding activities, it is rare for a large non-profit community hospital to also face criminal felony prosecution for such conduct.

Judge Terrence Boyle of the U.S. District Court of Eastern District of North Carolina rejected the original settlement, which he characterized as “a slap on the hand.”[6] Pointing to the fact that individuals often receive convictions and jail time for comparable crimes, the judge questioned whether the hospital should receive what he considered to be preferential treatment. Judge Boyle also questioned why the agreement stipulated that the auditor's reports would be kept confidential during the deferred prosecution period.[7]

In response to this judicial scrutiny, the government submitted supplemental briefs to support the parties' proposed resolution. On February 8, 2013, Judge Boyle approved a settlement under which the hospital submitted to a five-year CIA, admitted to the underlying misconduct, and agreed not to make public statements contradicting the statement of facts. Individual officers, directors, and employees of the hospital did not receive any release, meaning that they remain vulnerable to future prosecution. In addition, Judge Boyle added conditions to the agreement that mandate the filing of compliance reports with the court and permit the court to hold a hearing in a year to review compliance efforts.[8] Judge Boyle explained that he had “considered the equities at issue,” and the need to protect the “defendant's employees and healthcare providers who are blameless but who would suffer severe consequences should defendant be convicted and debarred as a Medicare and Medicaid provider."[9] In addition, the judge recognized the “threat that the provision of essential healthcare to WakeMed's patients would be interrupted and that the needs of the underprivileged in the

surrounding area would be drastically and inhumanely curtailed should defendant be forced to close its doors as a result of the instant prosecution."[10]

New Challenges for Resolving Corporate Health Care Prosecutions

It remains to be seen whether the Orthofix and WakeMed cases are aberrations, or if they portend a momentous shift in the resolution of corporate health care cases. Nevertheless, the mere prospect of increased judicial scrutiny of corporate settlement agreements in health care cases presents unique concerns for prosecutors and defense counsel alike.

While judicial insistence on tough punishment of corporate defendants would seem beneficial to the government, intense scrutiny of settlements could serve to limit prosecutorial discretion. For example, in the WakeMed case, Judge Boyle challenged the use of DPAs, which prosecutors have recently embraced as a flexible means to achieve deterrence and proportionality in corporate settlements.[11] Similarly, Judge Young questioned the design of the global settlement in Orthofix, suggesting that it was too lenient despite the fact that several of employees and contractors, as well as one of its subsidiaries, had pleaded guilty to felonies. In both cases, prosecutors carefully calibrated the settlements to achieve punitive and remedial outcomes without putting the respective companies out of business altogether. Their approaches were informed in part by the recognition that health care prosecutions can negatively impact communities that depend upon hospitals and other major providers for employment and patient care.[12] Finally, if too many impediments are placed upon government agencies in their attempts to reach compromise with corporate health care defendants, then the per-case costs of reaching resolution could increase exponentially; in turn, this trend could force agencies to redirect their scarce resources or undertake more limited agendas.[13]

Increased judicial scrutiny of settlements is an especially grave concern for health care providers and suppliers, who have faced intensified pressure to create a robust compliance culture as the government has made health care fraud an enforcement priority. Equipped with new legal tools and penalties authorized by the Affordable Care Act, the government enjoys enormous leverage in combating fraud at every level of the health care system. Given the complexity of the regulatory environment in which health care providers operate, it is not uncommon for even the most compliant provider groups to find themselves on the wrong end of the law. If corporate defendants had previously assumed that the judiciary would serve as a bulwark against prosecutorial overreach and be its best assurance of a balanced resolution, the Orthofix and WakeMed cases should give pause. It is now clear that defendants must be prepared for judges who will view their conduct with a more jaundiced eye.

Best Practices: What is a Corporate Defense Counsel to Do?

When seeking approval of global settlements in health care cases, defense counsel should proceed with the cautious expectation that reviewing judges will apply a demanding standard of review. Toward this end, counsel should take heed of the concerns voiced by judges in recent cases, which are addressed in the following set of best practices and considerations:

- **Argument:** Upon reaching a settlement with the government, defense counsel will need to carefully consider how the agreement is structured and presented for judicial approval. Counsel should prepare a detailed argument that bolsters the merits of the proposed agreement and how it furthers the public interest—one of the most significant factors for reviewing judges. Among other things, emphasis should be placed upon the defendant's cooperation with the government during the course of the investigation and going forward, and upon how the corporation has genuinely undertaken significant efforts to prevent the harm from recurring.

- **Education:** In making the case for settlement, defense counsel should also be prepared to assume the role of assisting the judge in understanding his client's unique circumstances and history and any peculiarities of the underlying law. While the harsh collateral consequences in the health care setting—which include loss of licensure, exclusion from federal programs, revocation of Medicare billing privileges, and FDA debarment—may be clear to health care providers, how they operate in a given case may not be readily apparent. For this reason, defense counsel should carefully brief these issues and explain how the collateral consequences would impact their clients and the communities they serve. This was critical in the WakeMed case, where Judge Boyle ultimately agreed to the use of a DPA after being informed of the consequences of exclusion.
- **Data:** Satisfaction of the public interest is easy to express in the abstract, but difficult to convey through the nuts and bolts of a settlement agreement. For this reason, defense counsel should present relevant statistics that substantiate the advantages of the proposed agreement and why it includes or excludes certain components.
- **Disclosure:** Transparency, both to the court and to the general public, is a quality that reviewing judges have come to expect. Judge Rakoff emphasized that judges cannot conduct a proper review upon "bare bones" submissions that reveal little about the factual underpinnings of the proposed settlement.[14] On the other hand, it may be critical to preserve the confidentiality of certain aspects of the case that involve the company's proprietary information. The extent of disclosure and the potential impact to the corporation's reputation and its standing in subsequent lawsuits raise difficult, albeit critical, issues for defense counsel.
- **Admission:** Another difficult question involves corporate admissions. Certain judges increasingly expect corporate defendants to admit to wrongdoing and/or to agree not to disparage or contradict any statements of fact contained in settlement agreements. If it becomes necessary, counsel should seek to devise an admission that satisfies the court without producing any harmful evidentiary effects in future lawsuits.[15]
- **Penalties:** Defense counsel should explain how the various penalties are interrelated and their real world impact on a corporation's daily operations and the greater community.
- **Compliance:** In arguing before the court, defense counsel should detail the past and future compliance reforms that the company has agreed to undertake. These reforms should accommodate the expectations of the various federal actors involved, including civil and criminal prosecutors, the OIG, state agencies and licensing authorities, etc. Defense counsel should also prepare their clients for the possibility that courts may expect to receive reports from the appointed monitor so that it is apprised of ongoing compliance efforts.

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[1] *SEC v. Bank of America Corp.*, No. 09 Civ. 6829 (S.D.N.Y. Sept. 14, 2009); *SEC v. Citigroup Global Markets Inc.*, No. 11 Civ. 7387 (S.D.N.Y. Nov. 28, 2011). *See also* Hon. Jed S. Rakoff, *Are Settlements Sacrosanct?*, 37 LITIG. 15 (Summer 2011).

[2] Judge Rudolph Randa of the U.S. District Court for the Eastern District of Wisconsin cited Judge Rakoff's Citigroup opinion when he temporarily held up a proposed deal between the SEC and the Koss Corporation. *SEC v. Koss Corporation*. No. 11-C-991 (E.D. Wis. Dec. 20, 2011) (letter to parties).; Judge Richard Leon of the U.S. District Court for the District of Columbia stymied the SEC's proposed $10 million agreement with IBM in a civil case under the Foreign Corrupt Practices Act involving the bribery of Chinese and South Korean government officials. Judge Leon noted that he was one of "a growing number of district judges who are increasingly concerned" by the SEC's settlement policies. Christopher W. Matthews, *Judge Blasts IBM, SEC Bribery Settlement*, WALL ST. J., Dec. 21, 2012, at B4.

[3] Jef Feeley & Janelle Lawrence, *Orthofix's Settlement of Medicare Probe Rejected by Judge*, BLOOMBERG NEWS (Sept. 6, 2012).

[4] *Id.*

[5] Transcript Excerpt of Sentencing Hearing at 2, United States v. Orthofix, Inc., No. 12-10169 (D. Mass. Dec. 18, 2012).
[6] Anne Blythe & Joseph Neff, *Judge Refuses to Accept WakeMed Settlement with Federal Prosecutors*, THE NEWS & OBSERVER (Jan. 17, 2013).
[7] Anne Blythe & Joseph Neff, *WakeMed's Medicare Settlement with Feds Would Allow Confidential Reports*, THE NEWS & OBSERVER (Feb. 2, 2013).
[8] Order of Judge Terrence W. Boyle, *United States v. WakeMed*, No. 5:12-CR-398-BO (Feb. 8, 2013).
[9] *Id.*
[10] *Id.*
[11] In a recent speech, former Assistant Attorney General Lanny Breuer described DPAs as playing an essential role in the enforcement of corporate crime. Lanny A. Breuer, Assistant Attorney General, Criminal Division, Address to the New York City Bar Association (Sept. 13, 2012), *available at* http://www.justice.gov/criminal/pr/speeches/2012/crm-speech-1209131.html.
[12] In WakeMed, the prosecutors stated, in a court memorandum that "[w]hile an individual convicted of an economic crime may face prison time as a sentence, a corporation convicted of the same offense may literally cease to exist as the result of a court order or as a practical impact of the conviction upon its business operations. Corporations also may be made up of thousands of individual employees, many of which had no part in any wrongdoing." Anne Blyethe & Joseph Neff, *WakeMed's Medicare Settlement with Feds would Allow Confidential Reports*, THE NEWS & OBSERVER (Feb. 2, 2013).
[13] Robert Khuzami, the Director of the SEC's Division of Enforcement, noted in a public statement that refusals of settlements agreements would "divert resources away from the investigation of other frauds and the recovery of losses suffered by other investors not before the court." Robert Khuzami, Public Statement by SEC Staff: Court's Refusal to Approve Settlement in Citigroup Case (Nov. 28, 2011).
[14] Hon. Jed S. Rakoff, *Are Settlements Sacrosanct?*, 37 LITIG. 15, 17 (Summer 2011).
[15] In his decision rejecting the Citigroup settlement, Judge Rakoff cited to a prior settlement reached between the SEC and Goldman Sachs in which Goldman "acknowledg[ed]" that it committed a "mistake" with respect to certain marketing materials—a mistake that it "regret[ted]." *SEC v. Citigroup Global Markets Inc.*, 2011 WL 5903733, at * n.7 (S.D.N.Y. Nov. 28, 2011). Such language may serve as a model for striking the right balance between showing contrition without incurring future legal liability.