The Rise of Deferred Prosecution Agreements: What We Can Learn from the Government's Increasing Use of DPAs

Tommy P. Beaudreau, Beth C. McClain, and Karen S. Bloom
Fried Frank Harris Shriver & Jacobson LLP, Washington, DC

A medical device company is accused of paying consultants to use its products, in violation of the Anti-Kickback Statute. A large academic medical center is alleged to be double-billing the Medicaid program. Ten years ago, healthcare entities would typically have resolved such allegations by agreeing to a civil and administrative settlement, perhaps agreeing to a guilty plea as well, if the alleged misconduct was really egregious. In the last few years, however, cases involving facts like these are increasingly resolved through the use of Deferred Prosecution Agreements (DPAs). According to one study, the number of federal cases resolved with DPAs rose from five in 2003 to 35 in 2007.[1] Notably, the Department of Justice (DOJ) has recently used DPAs to resolve a number of high-profile healthcare fraud cases. This article provides background information about DPAs and summarizes some of those recent healthcare cases, describing the terms of the DPAs and the controversy generated by some of those terms. The article describes the role of independent monitors in recent cases, and concludes with a discussion of issues health lawyers should consider if confronting the possibility of resolving allegedly criminal conduct with a DPA.

What Are Deferred Prosecution Agreements?

Deferred prosecution agreements resolve criminal investigations by providing for the filing of a criminal complaint against the target of the investigation. However, the government agrees to move to have the case dismissed at the end of a defined period if it is satisfied that the organization complied with the terms of the agreement. While their specific terms differ, most DPAs require an entity to:

- cooperate with the ongoing government investigation and, in some cases, the prosecution of individuals;
- waive the right to a speedy trial and relevant statutes of limitation; and
- take systemic remedial measures, like adopting and implementing a compliance program.

Many agreements also require an agreement to a statement of facts that includes admissions of wrongdoing by the company and include provisions for penalties or other restitution. Some DPAs require companies to waive attorney-client privilege or attorney work-product with respect to documents or testimony requested by DOJ. Perhaps most significantly, many recent DPAs have mandated the retention of independent monitors. These monitors are typically granted sweeping powers to gather information and oversee compliance.

The Government's View on the Advantages of Deferred Prosecution Agreements

Deferred prosecution agreements have been described as a "middle ground" between declining prosecution and the charging and conviction of a corporation, which can have calamitous consequences for innocent third parties, including patients and employees. Some prosecutors assert that DPAs benefit the public interest because they:

- allow corporate conduct to be addressed (by providing for restitution and mandating corporate reforms) more quickly than through a prosecution;
- can prevent the collateral consequences to employees, shareholders, and the public that may result from the conviction—or even the mere indictment—of a corporation;
- encourage organizations to cooperate in obtaining evidence to prosecute other culpable organizations or individuals;
- restore corporations' integrity by requiring the implementation of ethics and compliance programs; and
- allow the government to achieve these ends without foregoing its right to pursue a prosecution if an organization breaches the agreement or appears to engage in further misconduct.

Recent Deferred Prosecution Agreements Involving Healthcare Entities

One of the early DPAs involving a healthcare company was the June 2005 agreement entered into between the U.S. Attorney's Office for the District of New Jersey and Bristol-Myers Squibb, which involved allegations of accounting improprieties. In December 2005, the same U.S. Attorney's Office entered into

Deferred prosecution agreements have been described as a "middle ground" between declining prosecution and the charging and conviction of a corporation, which can have calamitous consequences for innocent third parties, including patients and employees.

The use of DPAs in these and other recent cases has led many observers to express concern about the lack of standards governing when these agreements should be used, when monitoring arrangements should be included, how monitors are to be selected, the scope of monitors' authority, and how compliance with agreement terms should be measured.

a DPA with the University of Medicine and Dentistry of New Jersey (UMDNJ). UMDNJ was charged with purposefully defrauding the Medicaid program; two different components of UMDNJ were accused of billing Medicaid for the same expenses. The UMDNJ experience under its DPA is described in greater detail below.

More recently, in September 2007, the U.S. Attorney's Office in New Jersey entered into DPAs with four orthopedic implant companies (Biomet, Inc., DePuy Orthopaedics, Inc., Smith & Nephew, Inc., and Zimmer, Inc.). These companies were accused of conspiring to violate the Medicare Anti-Kickback Statute through financial arrangements with orthopedic surgeons relating to the use of the companies' hip and knee joint reconstructive and replacement products. In addition to these DPAs, the government also entered into a Non-Prosecution Agreement (NPA) with a fifth company, Stryker Orthopedics, alleged to have paid surgeons to use its hip and knee replacement products.[2]

In each of these cases, the agreements obligated the company to: (1) commit itself to achieving "exemplary corporate citizenship"; (2) cooperate fully with all federal and state law enforcement and regulatory agencies; (3) appoint an outside monitor to evaluate compliance with the terms of the agreement; (4) notify DOJ and the monitor of any allegations of unlawful conduct or other wrongdoing; (5) establish a confidential hotline; (6) make restitution to state and federal governments; (7) waive its right to a speedy trial and any applicable statutes of limitations; and (8) adopt all recommendations made by the monitor unless DOJ agrees that a particular recommendation should not be required. The agreements also provide that DOJ will continue to investigate, and potentially prosecute, current or former employees of the companies and that DOJ will have the sole discretion to determine whether the agreements have been breached—a determination that potentially subjects the companies to prosecution, and is not reviewable by any court.

The Role of the Independent Monitor in Deferred Prosecution Agreements

All of the DPAs described above, as well as the NPA, require the defendant companies to retain an independent monitor. Under the agreements, the monitor typically is responsible for overseeing a company's compliance with the agreement, ensuring compliance with state and federal laws, and issuing at least quarterly reports to the U.S. Attorney's Office about the company's compliance with the agreement and the implementation and effectiveness of its controls and compliance functions. The monitor also is usually authorized to review and evaluate a company's relevant policies and practices, has discretion to review reports of corporate wrongdoing, and may disclose his reports, as directed by the U.S. Attorney's Office, to other federal agencies. The UMDNJ DPA, for example, provides that the monitor shall have unfettered access to all documents and information he deems necessary to assist in executing his duties. The other agreements provide for this access only with respect to non-privileged documents.[3]

DPAs typically provide that the monitor is to be selected by the U.S. Attorney's Office, but retained by the company, and no attorney-client relationship is to exist between the monitor and the company. The orthopedic implant agreements provide that the U.S. Attorney's Office shall select the monitor "after consultation with the company." While no guidelines are provided in the DPAs governing compensation for the monitor, one compensation arrangement sparked controversy recently when it was revealed that a no-bid

contract to serve as the monitor for Zimmer was awarded to former Attorney General John Ashcroft's consulting firm. The ensuing controversy and response are discussed in greater detail below.

Overlapping Roles for Monitors and Independent Review Organizations?

Concurrently with the DPAs, the orthopedic implant companies entered into settlement agreements with the DOJ Civil Division regarding the payment of money to settle certain civil claims and Corporate Integrity Agreements (CIAs) with the Inspector General of Health and Human Services to implement specified compliance measures. The CIAs and DPAs were negotiated separately, but among the compliance measures required under the CIAs is the hiring of an independent review organization (IRO) to help the company review its compliance with the CIA's requirements and to perform an annual review of the company's contractual and non-contractual arrangements. Because of some similarity between the roles of the IRO and the monitor provided for in the DPA, attention should be paid to their respective areas of responsibility. However, the agreements are typically negotiated separately.

Reactions to the Recent Deferred Prosecution Agreements in Healthcare Cases

The use of DPAs in these and other recent cases has led many observers to express concern about the lack of standards governing when these agreements should be used, when monitoring arrangements should be included, how monitors are to be selected, the scope of monitors' authority, and how compliance with agreement terms should be measured.

As noted above, the selection of John Ashcroft, the former U.S. Attorney General, and his consulting group as the monitor for Zimmer, Inc. provoked complaints on a number of fronts: Some condemned the seeming exorbitance of the fees involved in this monitoring arrangement—which under the agreement were estimated to be between $1.55 million and $7.9 million per month; others focused criticism on the seeming conflict of interest inherent in the selection of Mr. Ashcroft, the former Attorney General, as the monitor, especially because there was neither public notice of the monitor position nor an open, competitive bidding process for the assignment. Moreover, some have claimed that it is troubling that Mr. Ashcroft's firm is now benefiting from the system of DPAs that he helped to create as Attorney General.

Following these criticisms, in December 2007, Representative Bill Pascrell, Jr. (D-NJ) sent to the House Committee on the Judiciary's Subcommittee on Commercial and Administrative Law and to the DOJ a *Statement of Principles on Deferred Prosecution Agreements*, which calls for DOJ to issue guidelines about when corporations should be offered DPAs. Shortly thereafter, Representative Frank Pallone, Jr. (D-NJ) introduced legislation that would require the Attorney General to issue guidelines delineating when to enter DPAs, require judicial sanction of DPAs, and provide for federal monitors to oversee DPAs. Moreover, a judge or magistrate would appoint monitors who have experience in criminal and civil litigation from a pre-qualified pool

When a monitoring arrangement is unavoidable, much can be done to obtain significant benefits for the organization while minimizing potential risks.

Fraud and Abuse Practice Group Leadership

Kathleen McDermott, Chair
Sonnenschein Nath & Rosenthal LLP
Washington, DC
kmcdermott@sonnenschein.com

Kimberly Brandt, Vice Chair
Acting Director of Program Integrity Group
Centers for Medicare & Medicaid Services
Baltimore, MD
kbrandt@cms.hhs.gov

Jennifer F. DeCuir, Vice Chair
Baker Donelson Bearman Caldwell & Berkowitz PC
Baton Rouge, LA
jdecuir@bakerdonelson.com

Laura F. Laemmle-Weidenfeld, Vice Chair
Patton Boggs LLP
Washington, DC
llaemmleweidenfeld@pattonboggs.com

William T. Mathias, Vice Chair
OBER|KALER
Baltimore, MD
wtmathias@ober.com

Beth C. McClain, Vice Chair
Fried Frank Harris Shriver & Jacobson LLP
Washington, DC
beth.mcclain@friedfrank.com

William H. Maruca, Stark Law Listserve Moderator
Fox Rothschild LLP
Pittsburgh, PA
wmaruca@foxrothschild.com

Sara Kay Wheeler, Health Compliance Listserve Moderator
King & Spalding LLP
Atlanta, GA
skwheeler@kslaw.com

Thanks go to the Practice Group for sponsoring this feature.

of candidates. Monitors would be compensated according to a predetermined fee schedule, and would be required to issue reports to both the relevant U.S. Attorney Office and the district court.[4]

After Representative Pallone's legislation was introduced, a hearing before the Subcommittee was scheduled in March 2008 about DPAs. Scholars, current and former prosecutors, monitors, and members of Congress testified about DPAs, and a number of witnesses specifically focused on the monitoring provisions of these agreements. Some witnesses called for DOJ to issue guidelines delineating when U.S. Attorneys should utilize corporate monitors[5] or enter into DPAs[6] and how monitors should be selected and overseen.[7] Some witnesses called for many of the same reforms reflected in Representative Pallone's bill.[8] Alternative proposals would allow the defendant, prosecutor, and regulators to each nominate several monitor candidates (after the position is publicly announced and candidates are given an opportunity to apply) and then a federal district court judge or magistrate whould select a monitor from among these candidates.[9] Other reforms proposed at the hearing included making the complete text of all DPAs publicly available, standardizing not only the use but the terms of the agreements, and judicial approval of agreements' terms including the monitor's compensation and the determination of when an agreement has been breached.

The Justice Department Guidance on the Use of Monitors in Deferred Prosecution Agreements

On the eve of the congressional hearing, DOJ issued guidelines governing the use of monitors in DPAs.[10] The guidelines highlight the benefit of monitors and emphasize that—in light of the varying facts and circumstances of each case—a list of guidelines in this area must be flexible. Specifically, the guidelines provide that:

- prosecutors are to consider the potential benefits of monitors as well as the costs associated with monitors' work and the impact of monitors on corporate operations;
- prosecutors must (at a minimum) notify the appropriate U.S. Attorney or DOJ component head before executing an agreement that includes a corporate monitor;
- a committee should be established in the U.S. Attorney's Office where a case originated to evaluate monitor candidates;
- all monitors are to be approved by the Office of the Deputy Attorney General;
- prosecutors cannot unilaterally make, accept, or veto monitor candidates; and

The DOJ guidelines have, not surprisingly, received mixed reviews. Critics point out that the guidelines still do not ensure uniformity in the agreements, do not give sufficient guidance regarding when DPAs should be used, and do not require full disclosure of DPAs to the public.

- monitors should be selected based on their merits and in a way that avoids potential or actual conflicts of interest and instills public confidence.[11]

In terms of the monitor's responsibilities, the guidelines state that the monitor is to be "an independent third-party," and provide that

> a monitor's primary responsibility should be to assess and monitor a corporation's compliance with those terms of the agreement that are specifically designed to address and reduce the risk of recurrence of the corporation's misconduct, including in most cases, evaluating (and where appropriate proposing) internal controls and corporate ethics and compliance programs.

The guidelines provide that DPAs should identify which, if any, types of previously undisclosed or new misconduct the monitor will be required to report to the government, and that beyond these types of misconduct, the monitor has the discretion to choose whether or not to report such conduct to the government or the company.

The guidelines feature the importance of communication among the government, the relevant corporation, and the monitor and that "it may be appropriate for the monitor to make periodic written reports to both the government and the corporation." While stating that the board remains responsible for major decisions, the guidelines provide that if a corporation chooses not to adopt one of the monitor's recommendations, this fact should be reported to the government and the government "may consider this conduct when evaluating whether the corporation has fulfilled its obligations under the agreement."

Reactions to the DOJ Guidance

The DOJ guidelines have, not surprisingly, received mixed reviews. Critics point out that the guidelines still do not ensure uniformity in the agreements, do not give sufficient guidance regarding when DPAs should be used, and do not require full disclosure of DPAs to the public. Others assert that prosecutors retain too much latitude in selecting monitors under the guidelines. The lack of congressional or judicial oversight, in particular, remains a sore point for other critics of the arrangements. These observations may raise even more fundamental legal concerns, however, in judging whether it is appropriate for judges and Congress to intrude in decisions regarding the negotiation and execution of such agreements in light of constitutional separation of powers principles.

In any event, it seemed clear when DOJ issued the guidelines in March 2008 that the release would not be the final DOJ action on issues raised by recent DPA controversies, and in fact that has already proven to be the case. On May 14, 2008, Deputy Attorney General Mark Filip issued a memo instructing prosecutors to avoid including "extraordinary restitution" provisions in plea agreements and DPAs. This guidance may have been in response to the Bristol-Myers Squibb DPA, which controversially required the company to fund an endowed chair "dedicated to the teaching of business ethics and corporate governance" at Seton Hall University School of Law. The new language in U.S. Attorney's Manual Section 9-16.325 addresses "Plea Agreements, Deferred Prosecution Agreements, Non-Prosecution Agreements, and 'Extraordinary Restitution,'" and states that the latter should be avoided "because it can create actual or perceived conflicts of interest and/or other ethical issues." Moreover, the revision notes that referring to such payments as "restitution" "is a misnomer . . . as restitution is intended to restore the victim's losses caused by the criminal conduct, not to provide funds to an unrelated third party."

Additionally, on May 15, 2008, DOJ responded to the January request of Representatives Pascrell, Conyers (D-MI), and Sanchez (D-CA) by providing the lawmakers with 85

DPAs and NPAs, which DOJ believes represent the "large majority of the agreements entered during the time period" referenced in the Representatives' letter. DOJ also identified the monitors that were selected in the 41 of the 85 agreements where monitors were used, but was "unable . . . to provide information . . . concerning the contracts, including dollar amounts, awarded to monitors . . . [because] monitors retained under corporate DPAs or NPAs are not government employees or agents . . . [and the] government is generally not a party to those arrangements and we do not routinely receive the information you seek." The three Representatives subsequently posted a press release that, while praising the production as a "good first step in the process of learning more about the department's use of deferred prosecution agreements," noted that the Representatives "know there to be at least 12 other publicly available agreements that the department did not include which leaves us to wonder whether there are many more private agreements that we have not yet seen."[12]

Lessons Learned from the UMDNJ Experience

Because the UMDNJ DPA terminated in December 2007, the time is ripe to evaluate what that agreement, and its monitoring provisions, accomplished and any lessons companies facing DOJ investigations can learn from that case. One of the most troubling aspects of the UMDNJ agreement was the wide-ranging authority given to the monitor to investigate potential wrongdoing. Public reports issued by the UMDNJ monitor, for example, confirmed not only the alleged double-billing that was at the heart of the original criminal investigation, but also described a wide range of other practices and potential violations, including:

- an allegedly illegal scheme to pay cardiologists for patient referrals, with damages and penalties under the False Claims Act alleged to be as high as $84.5 million, resulting in criminal pleas by two UMDNJ cardiologists, as well as civil false claims proceedings against individual defendants;
- alleged irregularities relating to senior management compensation;
- allegedly improper patient steering based on ability to pay;
- alleged overbilling of certain costs, which could cause an additional $70–$100 million dollar liability and the loss of the University's status as a "nominal charge provider" under state law;
- alleged non-compliance with Federal Aviation Administration requirements for the operation of the University's air ambulance program, which could expose UMDNJ to severe penalties; and
- the discovery of an apparent no-work job created by UMDNJ for a state senator who was involved in lobbying activities on the University's behalf.

These are only a few of the wide-ranging allegations of improprieties reported by the monitor during its two-year term. Although the UMDNJ DPA provided for a term ranging between 24 and 36 months, the U.S. Attorney's Office agreed to terminate the DPA after 24 months.

Concluding Thoughts

When a monitoring arrangement is unavoidable, much can be done to obtain significant benefits for the organization while minimizing potential risks. Counsel can facilitate a good result by working with the government to obtain an agreement that focuses on shared objectives, which include—most fundamentally—improved compliance and the economic viability of the organization. For example, both parties share an interest in assuring public confidence in the process through the selection of independent monitors who have appropriate and well-defined authority. Counsel should insist on monitors with the expertise not only to identify compliance issues, but also to advise the organization on achieving compliance. An effective monitoring arrangement should allow the organization to retain control over its operations, including decisions about how to fix compliance issues identified by the monitor. To accomplish this, counsel must be proactive about defining the role of the monitor, the appropriate areas of oversight, and the methods for resolving any disagreements that might arise between the monitor and the monitored entity. Common areas of concern in monitoring arrangements include the degree to which the monitor's findings can or should be publicized. This determination often depends on the nature of the institution, its mandate, and the relevant public interests, but counsel can assist in obtaining the most appropriate reporting arrangement by alerting the parties to confidential information that may require enhanced protections from disclosure. Although it is undeniably preferable to avoid monitoring arrangements altogether, they can serve as an important bridge between a dysfunctional past and a more effective, compliance future.

Tommy P. Beaudreau is a litigation partner resident in Fried Frank's Washington, DC office. Mr. Beaudreau's practice involves a wide variety of criminal and civil litigation matters, including white-collar criminal defense, monitoring arrangements, internal investigations for public and private companies and government agencies, defense of False Claims Act suits, securities fraud and enforcement matters, and commercial disputes.

Beth McClain is special counsel at Fried Frank, where she works primarily on healthcare fraud and compliance issues, with a particular emphasis on litigation under the civil False Claims Act. She has significant experience representing a large monitored healthcare system during both the investigation phase and the subsequent monitoring period. Before entering the practice of law, Ms. McClain served as a commissioned officer in the U. S. Public Health Service.

Karen S. Bloom is a litigation associate in Fried Frank's Washington, DC office. She works on civil and criminal matters, including white collar, securities, constitutional, and False Claims Act litigation, government contracts disputes, and internal investigations.

1 Lawrence D. Finder and Ryan D. McConnell, *Annual Corporate Pre-Trial Agreement Update—2007*, Prepared for the March 2008 ABA White Collar Crime National Institute, at 1-2.

2 Copies of the DPAs and many of the sources mentioned in this article are available on the Fraud and Abuse Practice Group website *at* www.healthlawyers.org/Template.cfm?Section=Resources1.

3 The UMDNJ monitor also released public (but partly redacted) reports, which are currently available on the University's website *at* www.umdnj.edu/ethweb/federalmonitor.

4 H.R. 5086 (introduced Jan. 22, 2008).

5 *Deferred Prosecution: Should Corporate Settlement Agreements Be Without Guidelines: Hearing Before H. Comm. on the Judiciary, Subcomm. on Commercial and Administrative Law*, 110th Cong. 3 (2008) (statement of Representative Frank Pallone, Jr., Sixth District of New Jersey).

6 *See, e.g., id.* Representative Pallone suggested that DOJ consider the impact that an agreement will have on employees and shareholders and consider remedial actions taken by the company. He also called for uniform criteria to govern when the government will use DPAs and for reforming the monitor selection process.

7 *Deferred Prosecution: Should Corporate Settlement Agreements Be Without Guidelines: Hearing Before H. Comm. on the Judiciary, Subcomm. on Commercial and Administrative Law*, 110th Cong. 6 (2008) (statement of Brandon L. Garrett, Associate Professor of Law, University of Virginia School of Law).

8 *Id.*

9 *Deferred Prosecution: Should Corporate Settlement Agreements Be Without Guidelines?: Hearing Before H. Comm. on the Judiciary, Subcomm. on Commercial and Administrative Law*, 110th Cong. 2 (2008) (statement of Timothy Dickinson, Partner, Paul, Hastings, Janofsky, & Walker; and former monitor to Monsanto Corporation).

10 Memorandum from Craig S. Morford, Acting Deputy Attorney General, to Heads of Department Components and United States Attorneys (March 7, 2008), *available at* www.usdoj.gov/dag/morford-useofmonitorsmemo-03072008.pdf.

11 *Id.*

12 Press Release, Representatives John Conyers, Linda Sanchez, Bill Pascrell, Jr., *Lawmakers Seek More Details on Deferred Prosecutions: Justice Department Releases Some Agreements, Names Monitors* (May 22, 2008), *available at* http://judiciary.house.gov/newscenter.aspx?A=978.