With a Scalpel, Not a Sledgehammer: Resolving FDCA Investigations Through Deferred Prosecution and Non-Prosecution Agreements

By Steven J. Tave and Jeremy Joseph

Over the past decade, the Department of Justice (DOJ) has markedly increased its use of Deferred Prosecution Agreements (DPAs) and Non-Prosecution Agreements (NPAs) (collectively DPAs or agreements) to resolve allegations of corporate criminal wrongdoing. But the paucity of DPAs in Federal Food, Drug, and Cosmetic Act (FDCA) cases during this same period is striking: despite a number of significant and high-profile criminal enforcement actions against pharmaceutical and medical device companies for FDCA violations, DOJ resolved only a handful through DPAs, instead relying nearly exclusively on corporate guilty pleas and criminal convictions. DPAs have "become a mainstay of white collar criminal law enforcement"[1] because they offer prosecutors and companies the ability to balance three broad considerations that color nearly every charging decision: compliance, cooperation,

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and collateral consequences. These principles apply with equal force in FDCA cases, and companies defending criminal FDCA investigations should rely on them in advocating for agreements without guilty pleas.

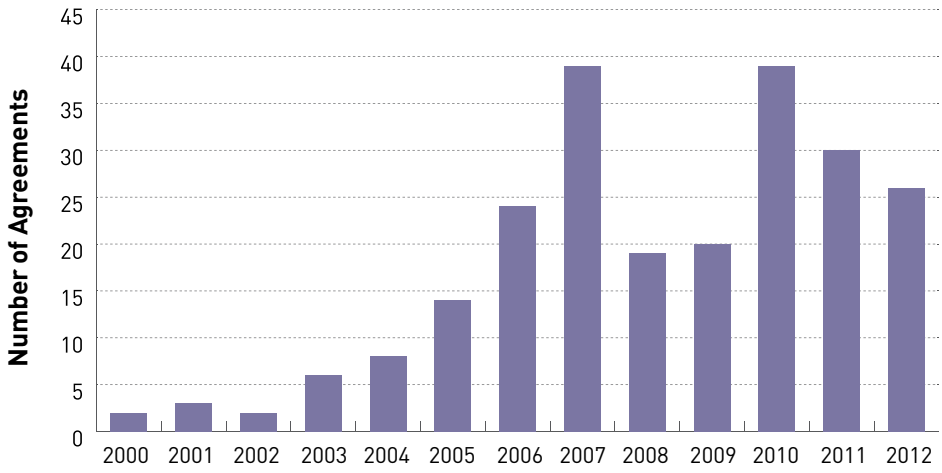
DOJ's Use of DPAs and NPAs

DPAs are contract-based agreements that represent a middle ground between a declination and criminal conviction. In a DPA, DOJ agrees not to prosecute the company, or to defer prosecution for a period of months, in exchange for an admission of wrongdoing, cooperation with the government's investigation, payment of monetary penalties, and meaningful compliance commitments. In some cases, DOJ has required that an independent "monitor" ensure compliance for the duration of the agreement. DPAs and NPAs differ from each other in one material respect: for DPAs, DOJ files a criminal information in federal court and the agreement is subject to judicial approval, while NPAs do not invoke the courts' authority and instead rely solely on the parties' respective commitments. The potential collateral consequences of conviction on innocent third parties are at the forefront of the government's decision to enter into a DPA.[2]

Since the millennium, DOJ has entered into corporate DPAs with increasing frequency to resolve a wide variety of criminal allegations—from the Anti-Kickback Act to trade sanctions, and from meat inspection to money laundering.

Nearly all Foreign Corrupt Practices Act (FCPA) corporate cases, and many cases involving fraud, trade sanction, and export control allegations against institutional companies, have been resolved using DPAs. While DOJ's Fraud Section and the U.S. Attorney's Office (USAO) for the Southern District of New York are the principal users of these agreements, nearly half of the 93 USAOs have entered into at least one such agreement. And the current head of DOJ's Criminal Division is a strong believer in them, proclaiming recently that "DPAs have had a truly transformative effect on particular companies and, more generally, on corporate culture across the globe," and that these agreements may represent "the best resolution" where a company "has gone to extraordinary lengths to turn itself around" or has "provided the government with extensive cooperation."[3]

DOJ Corporate DPAs and NPAs



Prosecutions Under the FDCA

Since the mid-1990's, most corporate FDCA prosecutions have alleged off-label promotion—that is, promoting an approved product for an unapproved use. In recent years, however, DOJ has both become more aggressive in categorizing potentially protected promotional activities as "off-label" or otherwise unlawful, and displayed a willingness to venture beyond promotion into areas like manufacturing and reporting that traditionally fell within the Food and Drug Administration's (FDA's) exclusive enforcement jurisdiction. Regardless of the theory of liability, these criminal investigations typically are accompanied by a civil False Claims Act (FCA) case initiated by one or more *qui tam* whistleblower complaints.

The collateral consequences of liability under the FDCA can be enormous. Most notably, liability may trigger exclusion from participating in federal healthcare programs such as Medicare and Medicaid. Depending on the type of conviction, exclusion may be either permissive—i.e., at the discretion of the Department of Health and Human Services Office of Inspector General (HHS-OIG)—or mandatory.[4] A defendant's second conviction under the FDCA is itself an automatic felony, potentially triggering mandatory exclusion.[5] Certain types of companies also may face FDA debarment, a sanction separate from HHS-OIG exclusion but equally injurious.[6] Exclusion or debarment could deprive patients of needed therapies, and would be fatal to a company in the business of supplying medical products. Innocent employees would lose their jobs and benefits, and investors would suffer financial loss.

As a result, negotiated resolutions in these cases follow a fairly predictable pattern. First, while not every case results

in criminal liability, many include a corporate criminal plea—a fact attributable, in part, to the FDCA's status as one of the only federal statutes to provide for misdemeanor criminal liability without any showing of knowledge or intent.[7] Corporate pleas typically require the company to pay a financial penalty and may provide for some terms of probation. Second, most cases include a civil FCA settlement that requires the company to make a significant payment to the federal government and, often, to participating states and the whistleblower(s). Finally, most resolutions include a Corporate Integrity Agreement (CIA) between the company and HHS-OIG. These CIAs, which impose and/or formalize extensive internal compliance obligations and structures, provide a basis for HHS-OIG to waive its permissive exclusion authority.

DPAs and NPAs in FDCA Cases

Many FDCA resolutions include some form of non-prosecution commitment from DOJ, either as part of a plea agreement or in an accompanying "side letter." Our focus here is not on these ancillary NPAs, which provide protection to a parent corporation from allegations of vicarious liability and other collateral consequences that could spring from factual admissions made by its affiliate or subsidiary. Rather, we are concerned with DPAs and NPAs that themselves represent the primary vehicle for resolving a criminal investigation.

To date, only a handful of FDCA cases have been resolved through such traditional DPAs and NPAs. Three were "standalone" cases, where the DPA or NPA was the only part of the resolution to address criminal liability. Two were "companion" cases, where the DPA or NPA was central to the resolution, but nonetheless was accompanied by a criminal plea from a related entity. Laudable efforts toward both remediation and cooperation are common to all of them.

"Standalone" DPAs and NPAs

In 2006, Intermune, Inc. entered into a DPA in the Northern District of California to resolve allegations of off-label promotion. In announcing the DPA, the USAO emphasized Intermune's "extensive" and "significant" cooperation with the government's investigation and improvements to its own compliance program. As evidence of the company's cooperation, the USAO highlighted Intermune's internal investigation, which preceded the government's investigation and the results of which Intermune disclosed to the government, as well as the company's numerous "helpful" presentations to the government. The USAO further acknowledged Intermune's "numerous and comprehensive compliance changes," together with the fact that the company's new management team had largely been hired after the conduct that gave rise to the investigation.[8]

In 2009, The Spectranetics Corporation entered into an NPA in the District of Colorado to resolve allegations including illegal imports, clinical trial violations, and off-label promotion. Again, cooperation and compliance played a prominent role in the USAO's announcement. The USAO cited numerous examples of the company's enhanced commitment to compliance, including: (1) providing additional specific company-wide formal training on FDA compliance procedures, and issuing further FDA compliance guidelines to all of its officers or employees; (2) continuing to retain and consult with counsel familiar with FDA laws and regulations; (3) improving its FDA compliance hotline complaint process, and providing additional training to compliance personnel on procedures for investigating complaints; (4) creating a corporate compliance charter and compliance auditing system; and (5) appointing a Chief Compliance Officer. The USAO noted that the company had taken responsive personnel actions and helped the government's investigation by disclosing its own research and scientific information relating to the underlying allegations, and that the company's internal investigation had concluded that the alleged wrongdoing was limited to certain officers and employees.[9]

The most recent NPA in an FDCA case is Google's 2011 agreement in the District of Rhode Island for allowing its online search engine to facilitate advertisements by Canadian pharmacies. On the surface, this case appears to stand apart from other FDCA prosecutions in that the company was not itself engaged in developing, manufacturing, or distributing medical products. At the same time, this resolution shares the common traits of other DPAs and NPAs. For example, the USAO detailed how Google had "enhanced its pre-existing compliance program and [ ] undertaken reforms and remedial actions in response to" the underlying conduct and pointed to "a number of significant steps" taken by the company "to prevent the unlawful sale of prescription drugs by online pharmacies to U.S. consumers" after it became aware of the government's investigation.[10] The NPA also included an express commitment of continued cooperation by Google.[11] Not overtly acknowledged in the government's public statements, but undoubtedly an important factor in the nature of the resolution, was the fact that liability was premised on a novel and untested application of the statute.

"Companion" DPAs and NPAs

Two cases from 2007 occupy a space between the three "standalone" resolu-

tions just discussed and the ancillary "side letter" NPAs alluded to earlier. In the District of Massachusetts, Pfizer subsidiary Pharmacia & Upjohn Company LLC entered into a DPA to resolve allegations of off-label promotion as part of a broader resolution in which another Pfizer subsidiary, Pharmacia & Upjohn Company Inc., pled guilty to kickback charges.[12] And in the Eastern District of New York several months later, Jazz Pharmaceuticals, Inc. (JPI) entered into an NPA to resolve allegations of off-label promotion as part of a broader resolution in which JPI's wholly-owned subsidiary Orphan Medical, Inc. (Orphan) pled guilty to a felony charge.

In both cases, the companies provided substantial affirmative cooperation and evidence of remediation that helped them successfully separate their new management and/or ownership from responsibility for the underlying conduct. Pfizer had acquired the Pharmacia entities in April 2003; one month later, in May 2003, it made a self-disclosure to the government, and it entered into a CIA with HHS-OIG several years before the criminal resolution was finalized.[13] JPI had taken proactive remedial measures immediately upon acquiring Orphan, even before it learned about the government's investigation; JPI also conducted its own review of Orphan's conduct and brought relevant facts and documents to the government's attention.[14]

Analysis and Outlook

Where a declination is not attainable, a DPA almost always will be preferable to a guilty plea. But DPAs are not without their own costs and burdens, including compliance undertakings, continuing cooperation obligations, and a possible compliance monitor. Companies need to be particularly conscious of possible repercussions in an FDCA investigation, where the specter of exclusion inevitably looms large and CIAs are frequently assumed to be indispensable pieces of a global resolution.

Entering into a DPA rather than pleading guilty may keep a company outside of HHS-OIG's exclusion authority and enable the company to avoid a CIA, but this should not be taken for granted. Under the exclusion statute, the definition of "conviction" includes entry into participation in a "deferred adjudication, or other arrangement or program where judgment of conviction has been withheld."[15] HHS has previously distinguished a deferred prosecution from a deferred adjudication, explaining that it does not consider a deferred prosecution to be a conviction where the initiation of charges has been deferred and the defendant retains the ability to plead not guilty and proceed to trial.[16] But whether any given disposition qualifies as a conviction turns on "the substance of the proceedings, rather than any formal labels or characterizations."[17]

As a result, since HHS may require a CIA even if the USAO would be satisfied without one, companies must proceed with extreme caution before entering into any agreement. Of course, the inability to avoid a CIA is not likely to cause a company to opt for a guilty plea over a DPA. But companies operating in the highly-regulated FDA environment may be able to leverage the existence of a robust regulator as a powerful bargaining chip in favor of less draconian requirements (such as no monitorship) or, ideally, declination. And a company that finds itself entering into both a CIA and a DPA must be especially vigilant to consider exactly what its future obligations will be.

For example, the CIA and the DPA might both impose the same fundamental periodic reporting obligation, but they might differ in the timing and format required. This would be unnecessarily duplicative, wasteful, and disruptive, with minimal benefit to the government. Similarly, a CIA and a DPA might apply inconsistent standards to assess ongoing compliance. A company should be able to take comfort in knowing that one authority has approved the steps it has taken toward compliance without the uncertainty of wondering whether the other might view the issue differently. There are many compelling arguments against these types of overlapping obligations, and a company in this position should negotiate carefully and zealously to ensure that it avoids these traps.

The collateral consequences of an FDCA conviction can be enormous, and DOJ's reliance on the "blunt instrument" of conviction in these cases is outdated. DPAs offer companies and prosecutors the ability to tailor a resolution that avoids these collateral consequences, rewards compliance, and secures cooperation while still holding companies accountable. We expect to see more FDCA cases resolved through DPAs, especially as DOJ's increasing use of aggressive, untested theories of liability and more robust First Amendment protection from the courts make these cases riskier for the government to litigate. Navigating the unique challenges presented in negotiating these agreements in the FDCA setting will require special care and expertise.

1. Lanny A. Breuer, Assistant Attorney General, Criminal Division, DOJ, Address at the New York City Bar Association (Sept. 13, 2012) ("Breuer Address").
2. U.S. Attorneys' Manual, Title 9, Section 28.1000 (August 2008).
3. Breuer Address.
4. *See* 42 U.S.C. § 1320a-7.
5. 21 U.S.C. § 333(a)(2).
6. *See* 21 U.S.C. §§ 335a(a)(1), (b)(2)(A) (providing for debarment for certain

convictions related to generic drug applications).

7. 21 U.S.C. § 333(a)(1). The automatic felony rule, 21 U.S.C. § 333(a)(2), appears to apply even if both predicate convictions were strict liability misdemeanors.
8. Intermune, Inc. DPA, ¶¶ 4-5 (Oct. 24, 2006).
9. Spectranetics NPA, Ex. A, at 4 (Dec. 17, 2009).
10. Google NPA, ¶¶ 2(q), 8 (Aug. 19, 2011).
11. *Id.* ¶ 13.
12. Pfizer, the parent company, also entered into a "side letter" NPA.
13. Pharmacia & Upjohn Company LLC DPA (Mar. 27, 2007).
14. Jazz Pharmaceuticals, Inc. NPA, ¶¶ 1, 4, 7 (July 13, 2007).
15. 42 U.S.C. § 1320a-7(i)(4).
16. *See Schneider v. Inspector General*, No. A-05-110, 2005 WL 3753090 (HHS Dep't App. Bd. Dec. 28, 2005).
17. *Travers v. Shalala*, 20 F.3d 993, 996 (9th Cir. 1994).