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Deferred Prosecution Agreements and Effective Compliance Programs in the Antitrust World: The New Married Couple

by Bona Law PC

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Deferred prosecution agreements ("DPAs") in the antitrust world have been a hot topic on this side of the Atlantic during the past two years. DPAs seem to be slowly becoming an efficient instrument for the **Department of Justice** to tackle antitrust conspiracies, and we expect this trend to continue.

What is a DPA?

A DPA is a legal agreement between a prosecutor and a defendant where the former eventually drops any charges against the latter, if the terms of such agreement are met. In other words, a DPA is a contract to resolve a **criminal enforcement action** without the prosecution of charges.

If the defendant—either a company or an individual—complies with all the terms of the DPA during a period of time (usually two to three years), despite being initially charged, the prosecutor will dismiss the charges and the defendant will avoid a conviction. DPA terms commonly require a defendant to pay a fine, implement certain remedial measures to alleviate the wrongdoing, or take steps to ensure future compliance.

While DPAs are almost universally considered a positive outcome for the defendant, they do carry some risk. By agreeing to a DPA, a defendant admits to wrongdoing and waives any right to challenge a set of agreed facts that are sufficient to sustain a conviction. Accordingly, if a defendant fails to comply with the terms of a DPA, it will face prosecution and almost certain conviction.

The Role of DPAs in the DOJ Criminal and Antitrust Recent Guidelines

Until recently, if an antitrust defendant did not win the race for leniency, the DOJ Antitrust Division's approach was to insist that the company plead guilty to a criminal charge with the opportunity to be an early-in cooperator, and potentially receive a substantial penalty reduction for timely, significant, and useful cooperation. This all-or-nothing philosophy highlighted the value of winning the race for leniency.

But all that changed in July 2019, when the Antitrust Division announced a **new policy to incentivize antitrust compliance**. These new guidelines were presented by AAG Makan Delrahim on July 11, 2019, at the Program on Corporate Compliance and Enforcement at the New York University School of Law: **Wind of Change: A New Model for Incentivizing Antitrust Compliance Programs**.

Delrahim explained that, unlike in the past, **corporate antitrust compliance** programs **will now factor into prosecutors' charging and sentencing decisions**, allowing companies to qualify for DPAs or otherwise mitigate exposure, even when they are not the first to self-report criminal conduct.

In particular, Delrahim highlighted three important points.

- First, that the adequacy and effectiveness of a compliance program is but one of the ten factors the Justice Manual directs prosecutors to consider when weighing charges against a corporation. Among the "Factors to Be Considered", four in particular stand out as hallmarks of *good corporate citizenship*: (1) implement robust and effective compliance programs, and when wrongdoing occurs, they (2) promptly self-report, (3) cooperate in the Division's investigation, and (4) take remedial action.
- Second, that the DOJ's new approach would allow prosecutors to proceed by way of a DPA when "the relevant Factors, *including the adequacy and effectiveness of the corporation's compliance program*, weigh in favor of doing so." DPAs, as the Justice Manual recognizes, "occupy an important middle ground between declining prosecution and obtaining the conviction of a corporation."
- Third, that the mere existence of a compliance program does not necessarily guarantee a DPA. Instead, "Department prosecutors are directed to conduct a fact-specific inquiry into "whether the program [at issue] is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees. In making a charging recommendation, Antitrust Division prosecutors will evaluate the compliance program's effectiveness or lack thereof, and holistically, consider it together with all the other relevant Factors."

This marked a substantial policy shift for the Antitrust Division, which previously never considered DPAs as an option to resolve antitrust conspiracy cases. Under the DOJ's

existing leniency program, the antitrust Division was allowing full immunity *exclusively* to leniency applicants.

That's not the case anymore—but make no mistake—only so long as the offending party has, as explained above, a truly robust and effective compliance program in place. And for that purpose, the recent **Revised Guidance from the *Criminal Division* issued in June 2020 on the Evaluation of Corporate Compliance Programs** is the last piece of this puzzle. The new Guidance provides additional information to assist prosecutors—both in **antitrust and other investigations**—in making informed decisions as to whether, and to what extent, a corporation's compliance program was effective at the time of the offense. You can read more about it on our previous post:

The Department of Justice Policy and Guidance on Antitrust Compliance Programs and Antitrust Criminal Violations

A Detailed Look at the First Eight DPAs Under the New Policy Incentivizing Compliance

As a result of the new DOJ's guidance on antitrust compliance programs and criminal investigations, we are starting to see an increased use of DPAs by the Antitrust Division. Let's have a close look at the ones made public so far.

U.S. v. Heritage Pharmaceuticals

In May 2019, Heritage Pharmaceuticals Inc. and DOJ entered into the first **DPA** as a result of a criminal antitrust investigation.

The DOJ charged Heritage with conspiring to suppress and eliminate competition by allocating customers, rigging bids, and fixing and maintaining prices for glyburide, a drug used to treat diabetes, sold in the United States, from April 2014 and continuing until at least December 2015, in violation of the Sherman Antitrust Act.

DOJ deferred prosecution of Heritage for a period of three years based on: (i) Heritage's substantial cooperation allowing the United States to advance its investigation into criminal antitrust conspiracies among other manufacturers of generic pharmaceuticals, (ii) the settlement of civil claims related to federal health care programs arising from its conduct, and (iii) the fact that a conviction (including a guilty plea) would likely have resulted in Heritage's exclusion from all federal health care programs for a period of five years, with devastating consequences for the financial viability of the company and the negative impact of competition in the market concerned.

Heritage was charged for conspiring with its competitors and agreed to pay a $225,000 criminal penalty; $7.1 million to resolve allegations under the False Claims Act related to

the price-fixing conspiracy; while continuing to implement a compliance program designed to prevent and detect criminal antitrust violations throughout its operations.

U.S. v. Rising Pharmaceuticals Inc.

In December 2019, Rising Pharmaceuticals Inc. and DOJ entered into a three-year **DPA**, agreeing to resolve allegations that, from April 2014 until at least September 2015, Rising participated in a criminal antitrust conspiracy with a competing manufacturer of generic drugs and its executives to fix prices and allocate customers for Benazepril HCTZ, a medicine used to treat hypertension.

Under the DPA, Rising agreed to pay $1,543,207 in restitution to victims of the charged conduct; $1.1 million in civil damages for False Claims Act violations predicated on Rising's antitrust conduct; and a $1.5 million monetary penalty, reduced from the fine of approximately $3.6 million called for under the U.S. Sentencing Guidelines, due to Rising's financial condition and liquidation.

In addition, under the DPA, Rising agreed to cooperate fully with Antitrust Division's criminal investigation. Other facts and circumstances identified in the agreement included Rising's agreement to pay restitution, and the fact that a conviction (including a guilty plea) would have resulted in substantial delay to Rising's ongoing bankruptcy proceeding and liquidation.

U.S. v. Sandoz Inc.

In March 2020, Sandoz Inc., a generic pharmaceutical company headquartered in New Jersey, entered into a **DPA** with DOJ to resolve four criminal conspiracy charges to allocate customers, rig bids, and fix prices for generic drugs, each with a competing manufacturer of generic drugs and various individuals. The charged conspiracies took place between 2013 and 2015.

Sandoz agreed to pay a $195 million criminal penalty and admitted that its sales affected by the charged conspiracies exceeded $500 million.

In return, DOJ deferred for three years any prosecution against Sandoz. DOJ considered Sandoz's full timely cooperation with the United States' investigation on other generic drug manufacturers, and that a conviction would have likely resulted in Sandoz's mandatory exclusion from all federal healthcare programs under 42 U.S.C. § 1320a-7 for a period of at least five years, with substantial consequences to the corporation's employees and customers outside the federal health care programs.

Sandoz agreed to continue to implement a compliance program designed to prevent and detect criminal antitrust violations throughout its operations, including those of its subsidiaries.

This Agreement ensured—once again—the integrity of the company's operations, and its financial viability while preserving the United States' ability to prosecute.

U.S v. Florida Cancer Specialists & research Institute

In April 2020, DOJ agreed to a DPA with Florida Cancer Specialists & Research Institute LLC (FCS), a Florida oncology group, which admitted its involvement in a criminal conspiracy to allocate medical and radiation oncology cancer treatments in Southwest Florida.

FCS agreed to pay a $100 million criminal penalty, fully cooperate with the Antitrust Division's investigation, as well as to maintain an effective compliance program. Once again, the DPA highlights how a conviction would have likely resulted in FCS's mandatory exclusion from all federal healthcare programs, affecting patients outside of those programs, in clinical trials, as well as the company's employees.

There are two new developments worth mentioning here. For the first time, the Antitrust Division published a **Q&A** explaining the reasoning behind the DPA. Second, the non-compete waiver in the DPA eliminates a restriction on the ability of current and former FCS employees, including physicians and other health care professionals, to open or join a competing oncology practice in Southwest Florida, increasing competition in the treatment of cancer patients in that area.

U.S. v. Apotex Corp

In May 2020, Apotex Corp., a generic pharmaceutical company headquartered in Florida, entered into a three-year **DPA** with DOJ.

In this case, the Antitrust Division alleged that from May 2013 to December 2015, the company together with other generic drug companies, conspired to fix the price of pravastatin, a generic cholesterol medication.

Apotex agreed to pay a $24.1 million criminal penalty, fully cooperate with the Antitrust Division's investigation, and maintain an effective compliance program. Once again, the DPA highlights how a conviction would have likely resulted in Apotex's mandatory exclusion from all federal healthcare programs, affecting patients outside of those programs, in clinical trials, as well as the company's employees.

The only nuance here is the fact that, in light of the availability of civil causes of action, the existence of civil cases already filed against Apotex, and contrary to what happened in the past, this DPA does not include any specific provision for restitution.

U.S. v. Taro Pharmaceuticals U.S.A. Inc

In July 2020, DOJ reached a **DPA** with Taro Pharmaceuticals U.S.A. to resolve charges of participating in two criminal antitrust conspiracies to fix prices, allocate customers,

and rig bids for numerous generic drugs, including medications used to prevent and control seizures and treat bipolar disorder, pain and arthritis, and various skin conditions.

Count One charged Taro U.S.A. for its role in a conspiracy with Sandoz Inc., former Taro U.S.A. Vice President of Sales and Marketing Ara Aprahamian, and other individuals, from at least as early as March 2013 and continuing until at least December 2015.

Count Two charged Taro U.S.A. for its role in a second conspiracy with a generic drug company based in Pennsylvania and other individuals, from at least as early as May 2013 and continuing until at least December 2015.

The company ended up paying a $205.6 million penalty and reached a similar agreement with DOJ as others within the generic drug industry.

U.S. v. Argos USA LL.C

In January 2021, the DOJ reached a **DPA** with Argos USA LLC, where the company agreed to pay a $20 million criminal penalty and admitted to participation in a conspiracy to suppress and eliminate competition by fixing prices, rigging bids, and allocating markets for sales of ready-mix concrete.

According to the DPA, employees of Argos and other ready-mix concrete companies carried out the charged conspiracy by coordinating the issuance of price-increase letters to customers, allocating specific ready-mix concrete jobs in the coastal Georgia area, charging fuel surcharges and environmental fees, and submitting bids to customers at collusive and noncompetitive prices.

Conflict Note: Bona Law represents clients in related civil **antitrust** and other claims against Argos and others.

U.S. v Berlitz Languages Inc.

Two providers of foreign-language services, Comprehensive Language Center Inc. (CLCI), and Berlitz Languages Inc. (Berlitz) have been recently charged with participating—between March 2017 and December 2017—in a conspiracy to defraud the United States by facilitating the submission of false and misleading bid information to the NSA.

The Antitrust Division also announced DPAs resolving charges against them. Under these agreements, the companies admitted to participating in the charged conspiracy, agreed to cooperate fully with any related criminal investigation and prosecution, and agreed to maintain a compliance and ethics program designed to prevent and detect violations such as the one charged.

Berlitz also agreed to pay a $147,000 criminal penalty and CLCI agreed to pay a $140,000 criminal penalty. Both companies agreed to be jointly and severally liable to pay $56,984 in victim compensation to the NSA, and are also charged with a violation of 18 U.S.C. § 371, which carries a maximum penalty of a $500,000 fine.

Final Conclusions

We are currently witnessing a policy shift from the Antitrust Division, which previously never considered DPAs as an option to resolve antitrust conspiracy cases.

Under this new DOJ policy, DPAs seem to be available to all those companies that can demonstrate a "good corporate citizenship": (i) by having an effective compliance program in place, (ii) if they self-report wrongdoings, (iii) they fully cooperate with on-going DOJ investigations, and (iv) are able to remedy past misconduct.

These first eight DPAs outline how the Antitrust Division is planning to hold parties allegedly involved in antitrust conspiracies accountable under this new procedure, while at the same time, guaranteeing their future compliance and protection to end consumers. But until we see more DPAs from the Antitrust Division, it is hard to understand the necessary elements companies will need in the future if they want to engage in successful negotiations.

For now, all companies can do is make sure to have a robust and effective antitrust compliance program before they even decide to negotiate a DPA with DOJ.
The **Antitrust Division Guidance on Evaluation of Corporate Compliance Programs in Criminal Antitrust Investigations (July 2019)** is a good place to start.

Antitrust News: The Department of Justice Wants You to Have a Strong Antitrust Compliance Policy

Antitrust Compliance Programs in the US and the European Union

Last but not least, DOJ's leniency program—which is an integral part of the Antitrust Division's criminal enforcement, and also offers non-prosecution agreements to companies that are the first to self-report wrongdoing—still remains in place. How it may interact with the negotiation of DPAs is definitely another thing to watch in the months to come.