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Deferred Prosecution Agreements

How to Survive - and Even Thrive - Under a DPA

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Deferred prosecution agreements (DPAs) are typically preferable to guilty pleas when resolving a corporate criminal investigation, but they come with significant compliance and reporting requirements. In an October 2021 [speech](#), Deputy Attorney General Lisa Monaco emphasized that the DOJ intended to scrutinize companies' compliance with these requirements. "DPAs and NPAs are not a free pass, and there will be serious consequences for violating their terms," she said. DOJ components, such as the Criminal Division's Fraud Section, have established dedicated units focused on corporate compliance issues, including, among other things, compliance with DPA requirements, and the Fraud Section has recently found DPA breaches by multiple companies and required them to plead guilty, effectively wiping out the benefits of the DPAs.

In light of the increase in scrutiny and dedicated resources, what can a company do to best position itself to successfully conclude a DPA? In this article, we reflect on our own experiences having been part of the Novartis in-house compliance and legal teams and external counsel who worked to ensure compliance with a DPA that the company entered in June 2020 and concluded in June 2023. We provide concrete takeaways from our three years of compliance enhancements, annual reports and government oversight, as well as the institutional ingredients that make the compliance gains meaningful and lasting.

See "[Klaus Moosmayer of Novartis Explains Why Holistic Risk Assurance Is the Future of Compliance](#)" (Jun. 23, 2021).

DPA Reporting and Disclosure Requirements

In June 2020, we entered into a [DPA](#) with Fraud Section and the U.S. Attorney's Office for the District of New Jersey. As is typical, our DPA had two key reporting requirements: The company was required to (1) report annually to the DOJ on its compliance program, including on its progress in complying with the enhanced compliance requirements imposed under the DPA, and (2) disclose to the DOJ additional allegations of potential anti-bribery violations.

A parallel SEC resolution imposed similar requirements. Reflecting DOJ's recent emphasis on DPA compliance, this article focuses on our DPA with the DOJ, but the lessons we learned with respect to the DPA were equally applicable to successfully completing our obligations to the SEC.

On December 21, 2023, the U.S. District Court for the District of New Jersey granted the DOJ's motion ending the DPA, after the DOJ informed the court that we had fully complied with all of our obligations under the DPA and that dismissal of the matter, with prejudice, was appropriate.

Preparing for the DPA Before It Begins

The success of a DPA begins before a deal is signed. This is the time to establish a strong relationship with DOJ prosecutors and open lines of communication. Support from key stakeholders ensures that those communicating directly with the DOJ are well-informed and represent the company accurately.

Achieve Stakeholder Buy-In

Successfully completing a DPA requires a company to have sufficient resources and other institutional support to enhance its compliance program – and to transparently report to the DOJ on its efforts. To this end, buy-in from the board, the CEO and other key stakeholders is crucial, and should ideally predate the DPA. Fortunately, the work of preparing for our DPA coincided with the company's efforts, begun several years prior, to transform our corporate culture and to build an integrated ethics, risk and compliance (ERC) program that would support the company's goal of building and maintaining trust with society.

We also ensured that key stakeholders knew what to expect from the DPA. Internal and external counsel provided regular briefings on the status of the negotiations with the DOJ, including discussing the anticipated requirements under a potential DPA and the implications for the company over the subsequent three years. These two elements – an increased commitment to compliance and integrity topics that predated the DPA and strategic setting of expectations once DPA negotiations had commenced – laid the foundation for a successful DPA process.

Filip Factor Presentation As a Foundation for the Reporting Requirement

Before a corporate criminal resolution is reached, the DOJ and the company meet to discuss the application of the Justice Manual's Principles of Federal Prosecution of Business Organizations (Filip Factors). This includes a presentation about the company's compliance program. We found that creating and delivering our compliance presentation to DOJ helped prepare us to meet the DPA's reporting requirements. In particular, it provided a framework and foundation for describing our compliance program and the enhancements made during the three-year reporting period.

See "[Filip Factor Presentations in the Wake of the Monaco Memo](#)" (Apr. 13, 2022).

Establish – and Maintain – a Dialogue With the DOJ

Corporate criminal investigations can be contentious, but it is important to establish and maintain a dialogue (and, hopefully, trust) with the DOJ so that the company and the prosecutors can find common ground to reach a resolution. It is equally important to maintain this dialogue throughout the DPA process. For example, we scheduled a six-month check-in with the DOJ after entering the DPA to provide an interim update on our compliance enhancements, and to receive feedback from prosecutors on their expectations.

Additionally, the mandated routine disclosure of alleged misconduct, discussed in more detail below, presented a natural mechanism for continued dialogue with the DOJ and an opportunity to demonstrate that our compliance and investigations program was working effectively in practice. We also made a habit of checking in before our compliance reports were due to ensure that the scope of the reports matched the DOJ's expectations and to identify any issues of particular interest to the DOJ. We also welcomed our meetings with the DOJ to discuss the reports after they were submitted. In summary, we believe that an open dialogue helped us meet the DOJ's expectations and demonstrated the company's commitment to getting things right.

See [“Meeting DOJ Expectations Post-Resolution Requires Realism and Accountability”](#) (Sep. 11, 2024).

Staying Organized to Execute the Plan

Once the term of the DPA begins, it is important for the company to have a plan for staying organized and on schedule with both its compliance improvements and its reporting obligations.

Develop a Plan for Program Enhancements

At Novartis, we conduct an annual assessment of our compliance management system. The annual assessment determines our agenda for the year to come by identifying specific compliance initiatives or policy updates, for example. Within Novartis, when we update elements of our compliance management system, the Novartis ERC function uses a comprehensive project management process to build teams focused on achieving specific objectives identified through the annual assessment. The projects that we pursue are almost always cross-functional – requiring input from, for instance, medical affairs, commercial, legal and other functions – which makes coordination essential. This structure, which we explained in detail to the DOJ, was seamlessly grafted onto the DPA's annual compliance reporting schedule and helped to ensure that we made progress on our compliance objectives during each reporting cycle.

Set Deadlines and Responsibilities for Report Writing

We used a project management approach for report writing that was similar to the approach used to implement our ERC management System objectives. To ensure accountability and clarity of

responsibilities, designated individuals from ERC and Legal led the DPA report-writing process and solicited inputs from various teams with different internal functions. The assignments were handed out more than six months before the report submission deadline, and the compilation of relevant materials began roughly three months out. This process was then repeated for the year-two and year-three reports.

Determine KPIs and Generate Data

The DOJ has emphasized that compliance data, employee interviews, controls testing and third-party audits are hallmarks of an effective compliance program and essential tools for the DOJ's own evaluations. To measure the effectiveness and maturity of our compliance management system, in 2021, we created a compliance evaluation program that uses over 300 key performance indicators (KPIs) that cover all six pillars of our system. In January 2021, we also launched a global Ethical Baseline Survey for associates. The results of this survey helped us measure our ethical culture and the impact of our compliance efforts to date, and provided a baseline to assess our future progress. It also helped us identify areas in need of immediate intervention and those that could benefit from long-term enhancement. Along with our preexisting internal audit, external audit and investigative functions, these tools helped us generate meaningful data to demonstrate the growth and effectiveness of our current system, and to strategically guide our future efforts.

See our two-part series “Developing Key Performance Indicators and Tracking Metrics for an Anti-Corruption Program”: [Part One](#) (Feb. 24, 2016), and [Part Two](#) (Mar. 9, 2016).

Prepare for the Next Report(s)

Writing the annual report is a lengthy process. We planned ahead for this process in two ways. First, we considered the DPA's three-year arc. The year-one report focused on articulating our existing ERC program and elements of our compliance management system to the DOJ. The DOJ team was already familiar with our program from prior discussions, but this served as a refreshed reminder and framework for the reporting discussions over the term. The year-two and year-three reports built upon this foundation to demonstrate how our ERC function had evolved in the intervening period. The year-three report also focused on showing that the enhancements that had been made during the reporting period were sustainable into the future.

Second, each annual report was both backward- and forward-looking. In other words, even before we submitted our first annual report, we carefully considered the enhancements that we wanted to make – and report on – the next year, and we did the same for the year-two report. Having this forward-looking view helped us set strategic and achievable milestones and provided the DOJ with a clear and coherent understanding of our integrity-related functions, initiatives and tools; how each strengthens the others; and how they would develop over the course of our DPA and beyond.

Investigate and Report Relevant Allegations

The Novartis DPA, like most DPAs, required that we report any additional issues to the DOJ proactively. In order to meet that obligation, the company needed to remain on top of internal reports and investigations, and determine whether reporting was necessary.

Ensure Proper Escalation of Allegations

A compliance program that is perceived by company employees to be effective and objective will receive reports of potential misconduct. In a large global organization, it is important that allegations are appropriately categorized and escalated to the attorneys handling the DPA so that they can be evaluated for potential disclosure. The Novartis legal team made presentations to leadership and other stakeholders to ensure that they understood the scope and importance of the DPA's disclosure requirements and the means by which allegations could be escalated. One of our key channels for escalating allegations is our SpeakUp Office, a channel for employees and people outside Novartis to report misconduct, which predated the DPA and to which all allegations of potential misconduct must be reported. The legal team worked closely with the SpeakUp Office to articulate the DPA's reporting requirements, maintain a continued open line of communication and ensure that potentially reportable cases were promptly identified.

Investigate and Remediate Thoroughly

Companies should always investigate and remediate issues found through audits and internal investigations, but it is particularly important to do so while under a DPA. Thorough investigation and remediation help the company put any allegations in context and demonstrate the effectiveness and sustainability of a compliance program.

See "[Internal Investigations in the Life Sciences Industry](#)" (Jul. 8, 2020).

When in Doubt, Lean Toward Reporting

While some allegations clearly fall inside or outside the scope of the DPA's reporting obligations, others will fall within a gray area. When in doubt, we erred on the side of disclosure. We felt that embracing a stance of transparency and disclosure helped build trust with the DOJ and SEC. As later cases involving DPA breaches of other companies have taught, taking an overly conservative approach to disclosure runs the risk that the DOJ will conclude that the company downplayed relevant allegations – in our view, a risk not worth taking. Moreover, in many instances, our disclosures demonstrated that our compliance enhancements were working.

Double Check Your Work

At the end of a DPA, a responsible executive must certify that all allegations within the scope of the disclosure requirement have been reported. The escalation methods discussed above provided assurance that we had met or exceeded the disclosure requirements. But, as a precaution, we asked our SpeakUp Office to provide a spreadsheet containing all of the reports over the three-year DPA period that arguably fell within the scope of the DPA's disclosure requirement. We then analyzed the investigative reports to ensure that all disclosable allegations were indeed disclosed. Had we found any additional undisclosed allegations, we would have made a disclosure before the end of the DPA's term. By going through this exercise, we were able to further reassure the certifying executive that the company had complied with its disclosure obligations.

See [“Can Compliance Certifications Empower CCOs?”](#) (Apr. 27, 2022).

Demonstrate Sustainability

Ultimately, the DPA process is not about producing a series of impressive reports, nor is it about three years of concerted compliance reforms and disclosures. Rather, it is intended to solidify an ethical corporate culture that is supported by a sustainable compliance program. The third year of our DPA was particularly focused on assuring the DOJ that the compliance gains we had achieved would last.

Novartis benefited from the fact that many of the processes that enabled us to successfully conclude the DPA were established prior to our resolution with the DOJ and were designed to continue thereafter. This was not a reactionary exercise. For example, reflecting our pre-existing commitment to a culture of compliance and integrity, we already had in place the annual risk assessment process described above, as well as two annual compliance meetings with the board of directors – one focused on risk management and the other focused on compliance efficacy. Establishing regular internal reporting processes and temperature-taking exercises helps drive consistent behavior and promote sustainable practices.

As our Chief Ethics, Risk and Compliance Officer, Klaus Moosmayer, has said many times, “We are not perfect and need to stay humble, but we take our ethical and compliance obligations towards society extremely seriously and will continuously develop our ethics, risk and compliance program in the spirit of integrated assurance.”

Making Lemonade

The DOJ has made it clear that it takes DPA requirements seriously. By embracing the same mentality when preparing for and executing a DPA, companies can demonstrate their dedication to high ethical standards and establish an effective working relationship with the DOJ throughout the DPA process that will provide benefits well into the future.

While no company wants to find itself across the table from the DOJ, with the right corporate culture, systems, resources and personnel in place, the DPA process can be an opportunity to meaningfully enhance durable compliance programs, policies and assessment processes. Having taken steps toward establishing integrity-centered practices before entering the DPA process – as Novartis did – certainly helps, but the difficult circumstances that lead to a DPA can ultimately provide a catalyst for additional, sustainable and profound compliance enhancements.

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