

White Collar Update: Teva to Pay \$519 Million in FCPA Resolution, a Pharmaceutical Industry Record

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In late December 2016, Teva Pharmaceutical Industries Ltd. (“Teva”), the world's largest generic pharmaceutical manufacturer, entered into a deferred prosecution agreement (“DPA”), and its wholly owned Russian subsidiary Teva LLC (“Teva Russia”) agreed to plead guilty in the United States District Court for the Southern District of Florida to conspiracy to violate the Foreign Corrupt Practices Act (“FCPA”) for a scheme to bribe government officials in Russia, Ukraine, and Mexico. Teva, an Israeli company, agreed to pay approximately \$519 million to U.S. authorities, including \$283 million in criminal penalties to the U.S. Department of Justice (“DOJ”) and \$236 million in disgorgement to the U.S. Securities and Exchange Commission (“SEC”) — the largest ever FCPA resolution for a pharmaceutical company. The settlement is also the first ever FCPA settlement with an Israeli company, as well as the fourth this year involving conduct in Russia and the third involving conduct in Mexico.

Factual Background

According to court documents, Teva participated in various bribery schemes over several years in Russia, Ukraine, and Mexico. Between 2006 and at least 2012, Teva made corrupt payments to a high-ranking Russian government official, who used his official position to influence the Russian government to purchase Copaxone, a multiple sclerosis drug. In return, a company owned and operated by the Russian official was granted the right to repackage and distribute Copaxone for sales to the Russian Ministry of Health. Executives at Teva and Teva Russia entered into this relationship with the Russian company despite due diligence concerns including knowledge of allegations that an executive at the Russian company was under investigation for corruption. Teva earned profits totaling approximately \$204 million on sales made to the Russian government by the Russian company. The Russian official earned approximately \$65 million in profits through the inflated profit margins.

Teva also admitted to paying bribes to a senior official in the Ukrainian Ministry of Health from 2001 to 2011 in exchange for approval of Teva drug registrations required to enter the market in Ukraine. The payments were made pursuant to a “registration consultant” contract with the official, through which he received a monthly fee from Teva, as well as at least five paid vacations to Israel and valuables worth approximately \$200,000.

Additionally, Teva admitted to failing to implement adequate internal controls or enforce existing controls at its Mexican subsidiary. According to the SEC’s civil complaint, since at least 2005 the subsidiary paid bribes to doctors employed by the Mexican government in exchange for increased prescriptions of Copaxone valued at approximately \$16.8 million. Executives responsible for Teva’s compliance program were made aware of the bribes by 2009, but the company’s internal controls were still insufficient to detect or prevent improper payments to government officials and “sporadic misconduct in Mexico continued.”

Teva Enters a Deferred Prosecution Agreement, Teva Russia Pleads Guilty

Teva Russia pled guilty to one count of conspiracy to violate the FCPA in the U.S. District Court for the Southern District of Florida, and Teva entered into a DPA in connection with a criminal information

charging one count of conspiracy to violate the FCPA and one count of failing to implement adequate internal controls. Teva also settled a civil case brought by the SEC.

Teva agreed to pay \$283 million in criminal penalties to DOJ, as well as \$236 million in disgorgement to the SEC. Teva's penalty represents a 20% reduction off the low end of the U.S. Sentencing Guidelines range for its cooperation with the investigation and substantial remediation efforts. Notably, Teva was only credited with partial cooperation due to its failure to meet some of DOJ's requests early on in the investigation. Teva was also ineligible for a more significant discount because it did not timely voluntarily disclose the conduct underlying the investigation. The DPA also requires the company to retain an independent compliance monitor for three years.

Observations

- **Pharmaceutical industry:** The penalties amount to the largest FCPA settlement with a pharmaceutical company to date, dwarfing prior pharmaceutical resolutions. At the "SEC Speaks" conference in February 2016, the SEC's FCPA Unit **warned** that it would be "going back to the pharma industry after a break for a period of years," and this record penalty reflects this renewed focus. The authorities' increasing focus on the pharmaceutical industry dates back to at least November 2009, when DOJ officials warned that pharmaceutical companies faced particular risks in the FCPA context because, in many countries, nearly all aspects of drug development, marketing and sales involve a 'foreign official,' as it is defined in the FCPA. Director of Enforcement for the SEC Andrew Ceresney reaffirmed this focus on pharmaceuticals and reiterated the high-risk nature of the industry in a March 2015 **speech** at CBI's Pharmaceutical Compliance Congress.
- **Partial cooperation:** The company received only partial credit for cooperation. DOJ did not credit Teva with voluntary disclosure. The company did receive cooperation credit for, among other things, making employees available for interviews, translating and analyzing evidence, and disclosing conduct in Russia and Ukraine of which the DOJ was unaware. The company was denied full cooperation credit because of "issues that resulted in delays to the early stages of the investigation"; these included the "vastly overbroad" invocation of attorney-client privilege and failure to produce certain documents in a timely fashion. The company was fully credited for remediation measures, which involved extensively enhancing compliance policies and procedures, although the company was nevertheless required to retain an independent monitor. Voluntary disclosure has become more significant in today's FCPA enforcement climate because the **DOJ's Pilot Program** caps discounts from the bottom of the sentencing guideline range for cooperation at 25% without disclosure, compared with a maximum 50% reduction if conduct is disclosed. Full credit requires voluntary self-disclosure "prior to an imminent threat of disclosure or government investigation" and outside any affirmative duty to disclose, proactive full cooperation including disclosure of all facts and instigation of an internal investigation, and appropriate remediation through an effective compliance program and discipline of employees engaged in misconduct.
- **Egregiousness of conduct:** The settlement amount accounts for, among other considerations, the high dollar amount of bribe payments paid to officials, the charged conduct's "pervasiveness throughout the Company's business," and the involvement of high-level executives in misconduct. The statement of facts suggest overt awareness of the high risk of FCPA violations by executives of the parent company, including a memorandum issued in 2011 to Teva by an employee responsible for financial controls in Mexico that concluded the company "cannot guarantee" that payments and accounting methods do not violate the FCPA. The "consulting" contract with a Ukrainian official was also signed by an executive of the parent company, and Teva was directly involved in the decision to enter into the repackaging and distribution agreement with the Russian company.

- **Imposition of a monitor:** The inclusion of an independent corporate monitor requirement in the Teva resolution for a full three-year term continues a pattern this year in which DOJ has required monitors in several high-profile corporate FCPA resolutions, such as [VimpelCom](#), [Embraer](#), [Och-Ziff Capital Management](#), and [Odebrecht](#).
- **SEC Civil Complaint:** The SEC abandoned its recent practice of using administrative proceedings to settle FCPA matters, in favor of filing a civil complaint in the Southern District of Florida, along with a consent judgment.

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