

Apotex Corp.
Deferred Prosecution Agreement – Q&A

What is the criminal charge against Apotex Corp.?

- Today, the Department of Justice’s Antitrust Division announced a criminal felony charge against Apotex Corp. (Apotex), a generic pharmaceutical company headquartered in Florida. Apotex is charged with one count of violating Section 1 of the Sherman Act for its participation in a criminal antitrust conspiracy to fix the price of pravastatin, a widely used generic cholesterol medication. The charge was filed in the U.S. District Court for the Eastern District of Pennsylvania in Philadelphia.
- Apotex’s relevant sales of pravastatin totaled at least \$105 million.

What are the material terms of the Antitrust Division’s deferred prosecution agreement with Apotex?

- Under the deferred prosecution agreement (DPA), Apotex will pay a \$24.1 million criminal penalty, admit to its participation in a conspiracy to artificially raise the price of pravastatin, and cooperate in the ongoing investigation.
- In the DPA’s statement of facts, Apotex admits that it conspired with other generic drug sellers to suppress and eliminate competition by agreeing to increase and maintain prices of pravastatin sold in the United States from May 2013 until December 2015.
- Apotex is also required to cooperate in the division’s ongoing investigation, including using its best efforts to secure the cooperation of its current officers, directors, and employees.
- Under the agreement, Apotex represents that it has implemented and will continue to implement a compliance program designed to prevent and detect criminal antitrust violations. Because of Apotex’s commitment to compliance, the agreement does not require a compliance monitor.
- Numerous civil actions are currently pending against Apotex, including multidistrict litigation consolidated in the Eastern District of Pennsylvania (*In Re: Generic Pharmaceuticals Pricing Antitrust Litigation*, Case No. 2:16-md-2724). In light of the availability of civil damages, the DPA does not provide for restitution.
- As part of the DPA, the division and Apotex will file a joint motion, which is subject to the approval of the court, to defer any prosecution and trial of the charges filed for the three-year term of the DPA.

Why was the charge resolved with a deferred prosecution agreement?

- The Antitrust Division entered into a DPA based on the individual facts and circumstances of this case.
- Among the circumstances the division considered is the likelihood that a criminal conviction — including a guilty plea — would result in Apotex’s mandatory exclusion from all federal health care programs for at least five years, under 42 U.S.C. § 1320a-7. The division weighed the collateral consequences — including to customers outside of federal health care programs, as well as to Apotex’s employees — that would result if Apotex were to be excluded from federal health care programs.

- The division also weighed Apotex's timely agreement to cooperate and its ongoing cooperation, which will aid the division's investigation into criminal antitrust violations among generic drug manufacturers.
- The division is confident that the agreement can ensure that integrity has been restored to Apotex's operations and preserve its financial viability while preserving the United States' ability to prosecute it should material breaches of the DPA occur.

What is the status of the investigation?

- The investigation into price fixing, bid rigging, and market allocation in the generic pharmaceutical industry is ongoing. This is the first charge and resolution involving pravastatin.
- Apotex is the fourth company charged in the investigation. *See* <https://www.justice.gov/opa/pr/major-generic-pharmaceutical-company-admits-antitrust-crimes> (Sandoz Inc.); <https://www.justice.gov/opa/pr/second-pharmaceutical-company-admits-price-fixing-resolves-related-false-claims-act> (Rising Pharmaceuticals); <https://www.justice.gov/opa/pr/pharmaceutical-company-admits-price-fixing-violation-antitrust-law-resolves-related-false> (Heritage Pharmaceuticals).
- Four individuals have also been charged. Three entered guilty pleas and the fourth is awaiting trial. *See* <https://www.justice.gov/opa/pr/former-generic-pharmaceutical-executive-pleads-guilty-role-criminal-antitrust-conspiracy> (former Sandoz executive pleads guilty); <https://www.justice.gov/opa/pr/generic-drug-executive-indicted-antitrust-and-false-statement-charges> (former executive indicted on antitrust and false statement charges); <https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer> (former Heritage Pharmaceuticals CEO and president charged).