



# Department of Justice

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FRIDAY, MAY 31, 2019  
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## **HERITAGE PHARMACEUTICALS FACT SHEET**

### **What is the criminal charge against Heritage Pharmaceuticals?**

- Today, the Department of Justice's Antitrust Division announced a criminal charge filed against Heritage Pharmaceuticals in the Eastern District of Pennsylvania. Heritage is charged with one count of violating Section 1 of the Sherman Act by participating in a criminal antitrust conspiracy with other corporate entities and individuals in the generic pharmaceuticals industry from about April 2014 until at least December 2015. A purpose of that conspiracy was to fix prices, rig bids, and allocate the market for glyburide, a drug that treats diabetes.
- Heritage sold approximately \$1.6 million worth of glyburide in the United States during the charged period.

### **What are the material terms of the Antitrust Division's deferred prosecution agreement with Heritage Pharmaceuticals?**

- Under the deferred prosecution agreement, Heritage will acknowledge its participation in the charged criminal antitrust conspiracy and pay a \$225,000 penalty. The agreement imposes cooperation obligations on Heritage and its subsidiaries, and requires Heritage to use its best efforts to secure the cooperation of its directors, officers, and employees. Further, under the agreement, Heritage represents that it has implemented and will continue to implement an effective antitrust compliance program.
- In consideration of Heritage's cooperation, its payment of a criminal penalty, and its implementation of an effective antitrust compliance program, the Antitrust Division will defer prosecuting Heritage for three years to allow the company to comply with the agreement's terms. Certain individuals are also covered by the terms of the agreement, including Heritage's current directors, officers, and employees.
- Numerous civil actions are currently pending against Heritage, 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 deferred prosecution agreement does not provide for restitution. Further, because of Heritage's demonstrated commitment to compliance, the agreement does not require a corporate monitor.

- The deferred prosecution agreement is subject to court approval. Once approved by the court, it will be filed and will then be available on the public docket.

**Why is the Antitrust Division entering into this form of resolution in this case?**

- As in all cases, the Antitrust Division carefully considered the factors set forth in the Principles of Federal Prosecution of Business Organizations, found in the Justice Manual, 9-28.300. Given the particular circumstances of this case, the Antitrust Division decided that a deferred prosecution agreement was appropriate in this instance. The Antitrust Division is confident that the agreement can ensure that integrity has been restored to Heritage's operations and preserve its financial viability while preserving the United States' ability to prosecute it should material breaches occur.
- Among the circumstances the Antitrust Division considered is the likelihood that a criminal conviction — including a guilty plea — would result in Heritage's mandatory exclusion from all federal health care programs for at least five years, under 42 U.S.C. § 1320a-7. The Antitrust Division weighed the collateral consequences — including to customers outside of federal health care programs, as well as to Heritage's non-culpable employees — that would result if Heritage were to be excluded from federal health care programs.
- The Antitrust Division also weighed Heritage's substantial cooperation in the ongoing criminal investigation into criminal antitrust and related offenses in the generic pharmaceuticals industry. That cooperation is ongoing, and includes providing the Antitrust Division with information regarding price-fixing, bid-rigging, and market allocation affecting drugs in addition to glyburide. In addition, the Antitrust Division considered Heritage's willingness to take meaningful remedial measures, including its concurrent agreement to resolve civil claims relating to federal health care programs arising from its violations of the antitrust laws.

**Have there been other charges brought against Heritage's co-conspirators? What is the status of the Antitrust Division's investigation?**

- Today's announcement follows the guilty pleas of Heritage's former CEO and former president for their roles in the glyburide conspiracy, as well as a conspiracy to fix prices, rig bids, and allocate the market for doxycycline hyclate, an antibiotic.  
<https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer>.
- As part of their plea agreements, those individuals agreed to cooperate in the ongoing investigation. *United States v Glazer*, No. 2:16-cr-00506 (E.D. Pa) <https://www.justice.gov/atr/case-document/file/931371/download> and *United States v Malek*, No. 2:16-cr-00508 (E.D. Pa) <https://www.justice.gov/atr/case-document/file/931376/download>. Both individuals were charged in December 2016 and are awaiting sentencing, pending their continuing cooperation.
- The Antitrust Division's investigation into antitrust violations affecting these and other generic pharmaceuticals remains ongoing.

**Does today's announcement also resolve the Department's civil claims against Heritage?**

- Today, the Department of Justice also announced a parallel civil settlement with Heritage, requiring Heritage to pay over \$7 million in civil damages to resolve False Claims Act allegations related to Heritage's agreement not to compete on certain generic drugs supplied to Medicare, Medicaid, and the Department of Defense's (DOD) TRICARE program beneficiaries, as well as the Department of Veterans Affairs. The drugs allegedly implicated in this scheme include glyburide, used to treat diabetes, as well as hydralazine, used to treat high blood pressure, and theophylline, used to treat asthma and other respiratory problems.
- In reaching this global resolution of both criminal and civil claims, the Department was mindful of its policy encouraging coordination among Department components and other enforcement agencies when imposing multiple penalties for the same conduct. Here, the Department's Antitrust Division coordinated with the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the Eastern District of Pennsylvania, in order to ensure that the Department pursued sanctions proportionate to the defendant's conduct and the legitimate goals of law enforcement.
- Except for the facts admitted to in the deferred prosecution agreement, the claims resolved by the civil settlement are allegations only, and there has been no determination of liability.

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