

Inside DOJ's Recent Charitable Copay Foundation Settlements

By **John Bentivoglio, Jennifer Bragg, Maya Florence and Elizabeth Berry** (April 22, 2019, 3:54 PM EDT)

On April 4, the U.S. Department of Justice announced three new civil False Claims Act settlements with pharmaceutical manufacturers in connection with its industrywide investigation of drug company relationships with independent charitable copay foundations. Alexion Pharmaceuticals Inc., Jazz Pharmaceuticals PLC and Lundbeck LLC together paid nearly \$123 million.[1] Jazz and Lundbeck also entered into corporate integrity agreements with the Office of Inspector General.

To date, seven companies have collectively paid more than \$700 million to resolve copay charity investigations, and an eighth has taken a \$100 million reserve in anticipation of such a settlement.[2] At least a dozen other companies have disclosed — but not yet resolved — copay charity investigations.

Key Takeaways

Three companies settled FCA investigations relating to their relationships with copay charities: Alexion (\$13 million), Jazz (\$57 million) and Lundbeck (\$52.6 million). In addition to the monetary settlement, Jazz and Lundbeck entered into five-year CIAs. Alexion did not enter into a CIA and its settlement does not contain a release of OIG enforcement authorities.

Each company allegedly engaged in one or more of the following types of conduct:

- contacted an ICF to create a copay fund geared toward the manufacturer's product(s);
- received company-specific data from an ICF and/or used such data to time donations;
- excluded Medicare patients from participating in a company's free goods program; or
- donated to a fund the manufacturer knew was available exclusively or almost exclusively for copays for the manufacturer's product(s).



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The settlements and/or DOJ press release make explicit reference to the price

of the underlying drugs — or to price increases — even though a “high” drug price — or price increase — has no impact on patient copays, which are a function of the Medicare Part D program.

Recent Settlements in Depth

Jazz Pharmaceuticals

The government alleged that, in 2011, Jazz — maker of Xyrem — asked the foundation Caring Voices Coalition to create a narcolepsy fund for Medicare patients, and Jazz became the sole donor. The DOJ further alleged that Jazz was aware that the fund almost exclusively used Jazz’s donations to pay copays for Xyrem, which only accounted for a small share of the overall narcolepsy market, and required patients taking competing products to obtain a denial letter from another assistance plan before helping them. In addition, Jazz is alleged to have excluded Xyrem Medicare patients from the company’s free drug program.



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With respect to a different drug, Prialt, the DOJ alleged that Jazz asked CVC to create a fund ostensibly for any severe chronic pain drugs that, in practice, almost exclusively paid Prialt Medicare copays. The DOJ alleged that CVC told Jazz that when severe chronic pain patients seeking assistance for other drugs contacted the foundation, it would refer them elsewhere. The government alleged that Jazz also was aware that the fund did not appear on CVC’s website. Jazz agreed to pay \$57 million to resolve the government’s allegations.

Lundbeck

Lundbeck sells Xenazine, the only approved drug during the relevant time period to treat chorea associated with Huntington’s disease. The DOJ alleged Lundbeck was the sole donor to a copay fund at CVC for patients with Huntington’s disease. The government also alleged that Lundbeck referred Xenazine patients with many other conditions to CVC, which then paid the Xenazine copays for these unapproved uses from the Huntington’s disease fund. The government further alleged that in June 2014, after the foundation determined that its Huntington’s disease fund would no longer pay the copays of patients taking Xenazine for non-Huntington’s disease uses, Lundbeck agreed to repurpose some of its prior donations to the Huntington’s disease fund to a general fund at the foundation for the purpose of paying these patients’ Xenazine copays and that Lundbeck made subsequent unrestricted payments to the foundation with the understanding that the foundation would use these payments to pay Xenazine copays for these same patients.

Additionally, the DOJ alleged that Lundbeck had a policy of not permitting financially needy Medicare or CHAMPVA patients to participate in its free drug program for Xenazine. Rather, the DOJ alleged, the company improperly referred such patients to CVC for copay assistance. Lundbeck agreed to pay \$52.6 million to resolve the government’s allegations.

Alexion Pharmaceuticals

Alexion sells Soliris, which during the relevant time period was indicated for certain patients with paroxysmal nocturnal hemoglobinuria, or PNH, and atypical hemolytic uremic syndrome, or aHUS. The government alleged Alexion approached Patient Services Inc., an independent charitable copay foundation, to create a fund to provide assistance for copay and medical expenses for Soliris patients. The DOJ alleged that PSI and Alexion discussed the company’s desire that the foundation not support patients with PNH or aHUS unless they were taking Soliris. Alexion was the sole donor to the fund and allegedly understood that PSI’s assistance was contingent on the patient taking Soliris. Alexion allegedly noted internally that it needed to be diligent in letting the foundation know if a patient had stopped taking Soliris so that Alexion’s donations would not be used on patients taking other medications.

In addition, the DOJ alleged that Alexion had a general practice of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients. Instead, Alexion allegedly referred Medicare patients to PSI through its referral portal software. Allegedly, the referral portal reported information back to Alexion confirming those Soliris patients who were approved for copay or other financial assistance from the foundation and detailed the foundation’s

payments to them. Alexion agreed to pay \$13 million to resolve the government's allegations.

Corporate Integrity Agreements

Jazz and Lundbeck entered into five-year CIAs, the provisions of which generally are similar to those in CIAs with companies that recently have settled copay charity cases — e.g., Aegerion Pharmaceuticals Inc, United Therapeutics Corporation. While both Jazz and Lundbeck are headquartered outside the United States, only the Jazz CIA makes certain provisions applicable to the parent company's board of directors. The Lundbeck CIA is limited to a U.S. entity, Lundbeck LLC, and various U.S. affiliates. In addition to requiring controls around company interactions with independent charitable copay foundations, both companies are required to adopt policies for "appropriate ways to conduct Promotional Functions," which are defined to include "selling, detailing, marketing, advertising, promoting, or branding" government reimbursed products. Both CIAs also incorporate helpful reforms, such as eliminating the requirement for covered persons training to include a set number of hours annually.[3]

Alexion did not enter into a CIA, nor was it added to the OIG's list of high-risk companies. Additionally, its settlement agreement does not include a release of OIG enforcement authorities. According to the government's press release accompanying the settlements, the "OIG decided not to require a CIA with Alexion because it made sweeping and fundamental organizational changes following the bad conduct. The changes included hiring a new eight-member executive leadership team and changing half of the members of its board of directors. In addition, 40% of Alexion's employees are new and the company relocated its corporate headquarters." This follows the OIG's decision not to insist on a CIA in connection with the Actelion copay settlement, presumably because Actelion had been acquired by another company — Johnson & Johnson — that was nearing the end of a separate CIA. Unlike with Alexion, the OIG offered no explanation at the time of the Actelion settlement.

Overview of DOJ Settlements and Enforcement Actions

In the seven copay case settlements to date, the DOJ has cited various types of specific conduct in support of its theory that companies used charitable copay foundations as "conduits" for manufacturers to cover the cost of copays for government health program beneficiaries. Manufacturer conduct the DOJ has cited includes:

- contacting an ICF to create a new fund geared toward the manufacturer's product(s);
- donating to a fund that was effectively a single donor/single drug fund;
- timing efforts to open a new ICF fund with an increase in the price of the drug;
- receiving company-specific data from an ICF and/or using company-specific data from an ICF to make donation decisions;
- excluding Medicare patients from a company's free goods program and/or referring Medicare patients to ICFs rather than processing the patients through the free goods program; and
- donating to an ICF fund that exclusively or almost exclusively covered the manufacturer's product while knowing that the fund was not advertised by the ICF — such as by posting on a website.

The DOJ also has been more explicit in citing the high cost of a drug — or to increases in the cost of a drug — as a justification for its copay enforcement efforts. According to U.S. Attorney Andrew E. Lelling, DOJ enforcement “will continue until pharmaceutical companies stop circumventing the anti-kickback laws to artificially bolster high drug prices, all at the expense of American taxpayers.”[4]

While it is true that Congress included patient copay requirements in the Medicare Part D program, above the \$5,150 catastrophic coverage threshold, Medicare patients pay the greater of 5% of total drug costs or \$8.50 for each brand-name drug. As a result, a drug’s “high” price has little or no impact on patient copays, and an increase in a drug’s price would have little or no impact on the corresponding copay.

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For the very serious conditions treated by many specialty drugs, such increases are likely to have little impact on a patient's decision on whether to pay the copay. The DOJ is surely correct that a manufacturer is prohibited under the federal anti-kickback statute[5] from directly covering a Medicare patient's copay obligation. But there is little empirical support in the settlement materials for the DOJ's implication that the allegedly improper copay assistance alleged in the three recent settlements was needed to bolster a specialty drug's price (above \$5,100) or to support subsequent price increases given the modest impact of overall drug prices on Medicare Part D beneficiary copays.

Correction: A previous version of this article misstated the impact that an increase in the price of a drug covered by the Medicare Part D program would have on patient copay. The error has been corrected.

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[1] The settlements did not contain any admission of liability by the defendants.

[2] Six companies have settled copay-only cases and paid FCA settlements totaling \$717 million. The seventh company, Aegerion, settled numerous criminal and civil allegations and paid a total of \$35 million. The Aegerion settlement documents did not specify what amount was attributed to the resolution of the copay allegations.

[3] For more information about recent changes in the OIG’s approach to CIAs, and suggestions for further improvements, see our previous Law360 article titled “10 Steps to Modernizing Corporate Integrity Agreements.”

[4] “Three Pharmaceutical Companies Agree to Pay a Total of Over \$122 Million to Resolve Allegations They Paid Kickbacks Through Copay Assistance Foundations,” U.S. Department of Justice, April 4, 2019, available at www.justice.gov.

[5] 42 U.S.C. § 1320a-7b(b)

