Pharmacy technician Anastasiya Sazanovich helps a customer at a Walgreens pharmacy on September 19, 2013, in Wheeling, Illinois.
Scott Olson/Getty Images

Charity for Gain: DOJ Eyes Patient Assistance Program Fraud

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- *DOJ cracking down on pharmaceutical companies allegedly using patient assistance programs to pay kickbacks*
- *Four major pharma companies have settled for over a combined $300 million to end investigations*

Pharmaceutical companies are facing increasing DOJ scrutiny over payments made to charities that help poor patients afford medication.

United Therapeutics, Aegerion, and Pfizer have resolved claims over alleged kickbacks paid to charities to subsidize the purchase of high-cost prescription drugs. These recent settlements in which the companies paid tens and even hundreds of millions of dollars, as well as an initial agreement with Jazz Pharmaceuticals, indicate the Department of Justice is on the prowl for other health-care companies that may be misusing charities, according to health lawyers who talked to Bloomberg Law.

These numbers suggest pharmaceutical companies need to make sure they take appropriate steps to ensure there is separation between their commercial decisions and the charity donations they make. Drugmakers also need to make sure their charitable donations to help people afford prescription drugs are made without attached strings and are truly charitable.

"The big hallmarks of suspicious activities have been when there's close coordination between drug manufacturers and patient assistance programs they're donating to," Jason Mehta, a partner at Bradley Arant Boult Cummings LLP in Tampa, Fla., who represents businesses involved in government investigations, told Bloomberg Law. "If you're going to give, you should give and expect nothing in return."

Major Contenders Swept Up

Three settlements and an initial agreement since 2017 highlight the importance of the issue to the departments of Justice and Health and Human Services.

The DOJ announced a $210 million settlement with United Therapeutics in December over allegations the company used a foundation to pay Medicare patients' copays for drugs used to treat high blood pressure in the lungs. The government also alleged that United made donations to the foundation, which used those donations to pay the copays of certain drugs to induce patients to purchase them. United also allegedly refused to let Medicare patients in its free drug programs, so they'd go to the foundation where claims are submitted to Medicare.

In May, Pfizer agreed to pay $23.8 million to settle allegations it paid the copays for kidney cancer and irregular heart beat medication for Medicare patients who were assisted by its charitable group in violation of the anti-kickback law. The DOJ alleged that Pfizer worked with a third-party pharmacy to send some patients to its foundation's free copay program, so it could file claims to Medicare for the drugs. The DOJ alleged Pfizer raised the price of Tikosyn, an irregular heart beat drug, 44 percent while it sent patients to its foundation.

In a May 24 press release, Pfizer said it agreed to a corporate integrity agreement as part of the settlement that set certain requirements for its compliance program, "most of which are reflected in Pfizer's existing compliance program." The company said it believes that independent charitable organizations that provide copay assistance to patients "help patients lead healthier lives."

"As an element of Pfizer's efforts to help ensure patients have access to critical medicines, Pfizer continues to donate to independent charity patient assistance programs," the statement said.

In November, Aegerion agreed to a $28.8 million settlement with the DOJ on a number of subjects, including the alleged misuse of a charity. The DOJ alleged Aegerion induced patients to purchase Juxtapid, a drug that treats a rare disorder that causes extremely high cholesterol, by paying patients' copays through a fund created at Aegerion's request by a charity group. An Aegerion spokesperson told Bloomberg Law the company is pleased to have the settlements behind it and has moved forward.

Jazz Pharmaceuticals reached an initial agreement with the DOJ in May to pay $57 million to settle a probe into its interactions with a patient assistance program. Jazz Pharmaceuticals told Bloomberg Law it was "pleased to have reached an agreement in principle with the DOJ" on the proposal for a civil settlement "subject to negotiation of a definitive settlement agreement and other contingencies." Jazz said it has a comprehensive program to ensure its compliance with legal requirements, including those pertaining to the company's support of charity organizations that provide financial assistance to Medicare patients.

Trending Up?

"It started with the 2005 [HHS] OIG guidance that was published when [the] Medicare Part D [drug benefit] was coming to fruition," Justin Linder, an attorney who represents health-care providers, including biopharmaceutical organizations, for Dughi, Hewit & Domalewski PC in Cranford, N.J., told Bloomberg Law. "There wasn't so much an issue until Medicare Part D became the law of the land because there weren't many prescriptions being filled on the government's dime."

In May 2014, the Department of Health and Human Services Office of Inspector General published guidance that built on the 2005 guidelines explaining that the use of patient assistance programs (PAPs) and charity programs could lead to anti-kickback and beneficiary inducement violations. The OIG explained that providers could suffer legal consequences if donor contributions are viewed as ways to induce PAPs to recommend or arrange the purchase of federal reimbursable items or if the PAP's financial assistance grant is made to influence patients to buy a certain product.

The HHS OIG also expressed a concern that independent charity PAPs could establish or operate disease funds that limit assistance to a certain group of products. The HHS OIG said such narrowly defined disease funds could make PAPs improper conduits used by providers to steer patients to certain products.

In November 2017, the HHS OIG took the unusual step of rescinding an advisory opinion on a PAP called the Caring Voice Coalition, saying the charity "provided patient-specific data to one or more donors." Those donors could use the information to correlate donations with the number of subsidized prescriptions or product orders.

Kevin McAnaney, a lawyer who specializes in health-care fraud and kickback issues at the Law Offices of Kevin G. McAnaney in New York, views this as a trend. "It wouldn't surprise me at all if there's more investigations and more complaints and more settlements," McAnaney told Bloomberg Law.

A Double-Edged Sword

The continued pursuit of action against pharmaceutical companies giving to these charities poses a moral dilemma of balancing the need to seek justice versus the real help such PAPs and charities provide to poor, indigent patients.

"I think it's an interesting contextual point to remember these patient assistance programs sprang out of a desire to help patients pay for expensive pharmaceutical drugs and in a climate where drug prices have gone up, it is unfortunate that the DOJ's investigation and enforcement activity might hamper the ability of patients to receive the drugs that they need," Mehta told Bloomberg Law.

Linder expressed similar sentiments. "I think these settlements are putting manufacturers in a tough spot. Legitimately, these manufacturers are just trying to provide financial assistance that gets these innovative drugs in the hands of people who need them, whether [they are] government beneficiaries or not," Linder said. "Increased scrutiny makes it more difficult for them to do it in a compliant manner."

McAnaney isn't even sure that pharmaceutical companies are doing anything wrong by giving money to PAPs to assist indigent patients. He said that if one of these cases went to court, the government could have a tough time proving its case.

"If they're paying copays, that's no different than forgoing copays and you're allowed to forgo the copays for financially indigent people," McAnaney told Bloomberg Law. McAnaney said that if the government allows providers to waive copays based on a bona fide standard of need, then pharmaceutical companies should be able to fund copays because they are a barrier to access for indigent patients.

"It's easier to settle, so they settle," McAnaney said in reference to the pharmaceutical companies.

The Pharmaceutical Research and Manufacturers of America (PhRMA), a pharmaceutical industry trade group, declined to comment on ongoing investigations and deferred comments to individual companies.

United Therapeutics didn't respond to Bloomberg Law's request for comment.

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