

Patient assistance programs attractive fraud target

By Mari Serebrov, Regulatory Editor

News of government prosecutors actively going after individuals for defrauding the U.S. health care system has become commonplace, but the government's focus on criminally prosecuting fraud against Medicare, Medicaid and other government programs could make biopharma companies' patient assistance programs a more attractive target.

That was the case for [Gilead Sciences Inc.](#), which recently settled a civil suit against AJC Medical Group Inc. and a number of other clinics, pharmacies, prescribers and medical labs involved in a massive fraud scheme in Florida targeting the company's assistance program for HIV pre-exposure prophylaxis (PrEP) drugs.

The confidential settlement reached late last month stemmed from an investigation Gilead began in 2019 after it discovered the defendants were processing "an enormous and disproportionate volume of reimbursement claims" for PrEP drugs through the company's free drug program, according to the Foster City, Calif., company.

The investigation, which was aided by whistleblowers, uncovered a broad network involved in recruiting homeless individuals in Florida and paying them in cash or cash cards to submit to a wellness check and paying them again to pick up each fill of PrEP medication under Gilead's free-drug assistance program. In many cases, the drugs were never dispensed. But the defendants submitted reimbursement claims, "regardless of whether the individual named on a prescription wanted, needed or received the medication," according to Gilead.

As a result of the schemes, fraudulent claims totaling more than \$68 million were submitted to the company's free drug program. In addition, whistleblowers informed Gilead that the PrEP drugs dispensed through the schemes were purchased from the "patients," repackaged and then resold on the black market.

The settlement "is a critical step toward ensuring public safety and the integrity of Gilead's free drug program," a company spokesperson said, adding that "Gilead's swift and decisive legal action against these fraudulent schemes . . . will help protect Gilead's ability to provide free life-saving HIV medications to eligible individuals for years to come."

The defendants agreed to the settlement shortly after a U.S. district judge froze their assets related to the fraud. Those assets included bank accounts, real estate, jewelry, luxury watches, private jets and a fleet of expensive cars, including Ferraris, Bentleys, Mercedes-Benzes and Rolls Royces.

Along with the settlement, the defendants were permanently enjoined from "enrolling, attempting to enroll, or facilitating the enrollment of any individual" in any Gilead assistance program; dispensing Gilead drugs in packaging other than the original,

unopened containers from the manufacturer; and selling, purchasing or otherwise obtaining Gilead medication that had previously been filled or dispensed, according to an April 28 court order.

However, the injunction doesn't stop the defendants from following a similar scheme with patient assistance programs offered by other drug manufacturers. And since this was a civil case, the defendants face no risk of prison time – unless the government decides to pursue a separate criminal investigation.



Geoffrey Potter, Lead Counsel for Gilead

Tempting target

Some bad actors choose to steal from patient assistance programs rather than the government because they're less likely to be criminally pursued, said Geoffrey Potter, a partner and chair of Patterson Belknap's anti-counterfeiting practice and brand protection team. The government does prosecute fraud against drug companies, but given its caseload and resources, such prosecutions are "few and far between," Potter told *BioWorld*. "You have to do it yourself." That means pursuing fraud in civil cases.

But first, biopharma companies have to be watching for fraud. Many companies don't realize they're victims, Potter said. "They're pharmaceutical companies; they're not law enforcement agencies," he added.

Most companies put their effort and resources into assuring that as many needy patients as possible have access to drugs through their patient assistance programs, Potter said. Consequently, protecting those programs from bad actors is a second thought, and many companies don't have a robust monitoring system. That lack of monitoring, the potential for big payouts and a lower risk of criminal prosecution make the assistance programs tempting fraud targets.

To protect drug assistance programs from bad actors, Potter advises biopharma companies to continually collect and analyze data from their programs. "That's the key," he said. Companies need to look for anomalies that don't make sense. Is one doctor issuing too many prescriptions through the program? Is one clinic purporting to see too many patients? Is one pharmacy filing too many claims?

Another anomaly is someone going from doing nothing or just a small volume to doing a high volume in a short period. In the real world, increases in prescribing or dispensing are gradual, Potter said. With fraud, volume often goes from zero to being in the top 5% in no time at all, he explained.

Once a company identifies such anomalies, it needs to examine them closely, Potter said. And when it uncovers fraud, it must take action.