

Gilead suit shows vulnerability of prescription assistance programs

Mari Serebrov, Regulatory Editor

It didn't take long for a U.S. district judge to grant [Gilead Sciences Inc.](#)'s request for a temporary restraining order (TRO) to stop two interconnected health care networks in Florida from defrauding the company's Advancing Access Medication Assistance Program (MAP) that provides free HIV pre-exposure prophylaxis (PrEP) drugs to eligible, uninsured people.



Geoffrey Potter, Lead Counsel for Gilead

Hours after the Foster City, Calif.-based company filed a civil complaint and a request for the restraining order and a preliminary injunction against AJC Medical Group Inc. and 57 other clinics, pharmacies, lab testing facilities and individuals, U.S. District Judge Kathleen Williams granted the TRO Nov. 3 and gave the defendants three days to make arrangements to turn over to Gilead any supplies of [Truvada](#) (emtricitabine/tenofovir) and [Descovy](#) (emtricitabine and tenofovir alafenamide) they have that are no

longer in the original, unopened container from the manufacturer or that have been previously filled or dispensed.

The defendants also were ordered not to destroy, discard or remove from their premises any records, communications or other documents relating to their assets and operations or to the scheme alleged in Gilead's complaint. The judge set a Nov. 16 show cause hearing on Gilead's request for a preliminary injunction.

In its request for the TRO and injunction, Gilead said the defendants were engaging in "massive and rapidly growing healthcare fraud schemes" that put "at grave risk the health – and even the lives – of thousands of Floridians who are economically challenged."

Gilead's suit against the health care networks highlights how vulnerable patient assistance programs are to fraud, how easy it may be for that fraud to go undetected and how challenging it is to safeguard against such schemes.

The scheme

The 225-page complaint, filed in the U.S. District Court for the Southern District of Florida, alleged that the two networks recruit homeless and low-income individuals who could financially qualify for the company's MAP, even though PrEP may not be medically necessary or appropriate for them.

The clinics give the individuals a "wellness check," which one whistleblower told Gilead is "a joke," and prescribe the PrEP

regimen. The networks then seek reimbursement from Gilead for the drugs and for administering them. As part of that process, they certify that the prescriptions are needed and appropriate.

Although the MAP reimburses Gilead's PrEP drugs at the wholesale acquisition price – currently \$1,800 per bottle – several of the defendant clinics purchase the drugs at steeply discounted 340B prices. Before giving the drugs to the recruits, the clinics have them repackaged in generic bottles, in violation of federal law and regulations. They then offer to buy the drugs back from the recruits for a paltry sum, so they can stockpile the drugs to be sold on the black market or return them to their pharmacy partners to be dispensed to another recruit for a second reimbursement for the same bottle of drugs, according to the complaint.

Gilead also alleged that the clinics often pay the same recruits to go to different clinics in the network to get multiple PrEP prescriptions that are then submitted to Gilead for reimbursement. As a result of the "dangerous and fraudulent schemes," the networks have stolen tens of millions of dollars from Gilead, the company alleged.

Gilead said it first became aware of the schemes when it noticed that certain clinics "were prescribing enormous volumes of PrEP medication to a suspiciously large number of individuals whom they had enrolled in the MAP. This output was grossly disproportionate relative to other healthcare providers in Florida and elsewhere."

Consistent reports of fraud from several whistleblowers, including current and former employees at the clinics, revealed the true nature and scope of the schemes, Gilead said.

Earlier this year, the company began implementing safeguards to protect against the fraud, including blocking certain prescribers from enrolling people through the MAP's online portal and requiring additional validation such as providing photo identification for the individuals or requiring validation calls with the patients.

Gilead said the networks responded to its efforts with workarounds – recruiting new prescribers that aren't blocked, making fake ID cards for the recruits, coaching them on the validation calls or falsely posing as the patient on the call.

"As defendants' increasingly brazen tactics demonstrate, Gilead cannot stop these dangerous and fraudulent schemes through its own efforts alone," the company told the court in seeking an injunction.

The Office of the U.S. Attorney for the Southern District of Florida didn't respond to *BioWorld's* query about whether a federal criminal investigation or charges are pending against the defendants.