United Therapeutics Enters False Claims Act Settlement Pertaining to Patient Assistance Program

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On December 20, 2017, United Therapeutics Corporation, a Silver Spring, Maryland-based pharmaceutical company that manufactures and sells a number of drugs to treat pulmonary arterial hypertension (PAH), agreed to pay $210 million to resolve allegations under the False Claims Act (FCA). According to the Department of Justice (DOJ), United Therapeutics allegedly used a charity, Caring Voice Coalition (CVC), as an illegal "conduit" to cover the copays of Medicare patients taking its PAH drugs, in violation of the Anti-Kickback Statute (AKS).[1] The AKS makes it a crime for pharmaceutical companies to pay remuneration to induce Medicare beneficiaries to purchase (or their physicians to prescribe) drugs that are reimbursed by Medicare.[2] Claims submitted to Medicare in violation of the AKS automatically constitute false claims for purposes of the FCA.[3]

Specifically, DOJ alleged that United Therapeutics violated the AKS by making donations to CVC's patient assistance fund in an effort to do indirectly what the drug company could not do directly – give PAH-drug patients money to help pay for the patients' out-of-pocket Medicare expenses. Patient assistance funds like CVC's have existed for years to assist patients in need with the high costs of their drugs, and the Department of Health and Human Services' Office of Inspector General (OIG) (the agency responsible for enforcing the AKS) has explicitly permitted (by way of special bulletins and advisory opinions) drug companies to donate drugs and/or money to non-profit charities like CVC so long as the drug companies remain independent.[4] However, according to the settlement agreement, United Therapeutics made donations while receiving data from CVC on how many patients were taking United Therapeutics' products and how much CVC had spent on those patients.[5] DOJ further alleged that the charity paid the copay obligations of Medicare patients on United Therapeutics' PAH products, and the company was able to consider the revenue it would receive from Medicare patients when making decisions about how much to donate to the charity. Moreover, United Therapeutics allegedly maintained a policy of not permitting Medicare patients to participate in its free drug program regardless of whether patients' could not afford their copays, even though other financially needy patients could participate. Instead, according to DOJ, the company referred Medicare PAH-prescribed patients to CVC, ultimately resulting in claims to federal healthcare programs.

Notably, CVC, like most other charitable organizations with patient assistance programs, had obtained a favorable advisory opinion from OIG with regard to its PAH assistance fund. In its advisory opinion, issued in April 2006,[6] and modified in December 2015,[7] OIG stated that the proposed program would not constitute grounds for imposition of civil monetary penalties or

1 Department of Justice, "Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks," Press Release (Dec. 20, 2017), https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability.

2 42 U.S.C. § 1320a-7b.

3 Pursuant to Section 6402 of the Affordable Care Act, claims submitted in violation of the Anti-Kickback Statute automatically constitute false claims for purposes of the FCA. 42 U.S.C. § 1320a-7b(g).

4 *See*, e.g., Dept. of Health and Human Servs., "Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs," 79 Fed. Reg. 31120 (May 30, 2014), *available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf.

5 Settlement Agreement between United States of America and United Therapeutics Corp., *available at* https://www.justice.gov/usao-ma/press-release/file/1019336/download (last accessed Jan. 9, 2018).

6 HHS OIG, Adv. Op. No. 06-04 (Apr. 20, 2006), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-04A.pdf.

7 HHS OIG, Notice of Modification of OIG Adv. Op. No. 06-04 (Dec. 23, 2015), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn06-04_mod.pdf.

administrative sanctions, based on the representations and facts presented at the time by CVC. Under the proposed program, the charity would offer financial assistance for treatment of specific chronic diseases. OIG evaluated several characteristics of the program when determining that it presented sufficiently low risk:

- No donor (e.g., a pharmaceutical company like United Therapeutics) would exert direct or indirect control over the program; the program would be independent.
- Assistance would be awarded independently, severing any link between donors and beneficiaries.
- The program would award assistance without regard to any donor's interest and without regard for the beneficiary's choice of provider, practitioner, supplier, or product. The program would not take into account the identity of the provider or drugs used by the beneficiary or the identity of any referring organization.
- The program would not provide donors with any data that would allow the donor to draw a connection between the amount or frequency of its donations and the amount or frequency of the use of its products or services. No individual patient data would be provided to the donor.
- Financially needy patients would be assisted on a first-come, first-serve basis without considering the identity of their health care providers, suppliers or products used, or the party that referred the patient. Medicare patients would be able to select providers and services regardless of whether that provider or manufacturer had made donations to the program.

However, OIG, which often coordinates with DOJ in health care fraud investigations, rescinded CVC's advisory opinion on November 28, 2017, alleging that CVC had broken with certifications it had made to OIG in obtaining the favorable opinion.[8] Specifically, the program had:

> (i) provided patient-specific data to one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and (ii) allowed donors to directly or indirectly influence the identification or delineation of [the program's] disease categories.

In light of the CVC's settlement, the charity announced that it will not be offering financial assistance to any disease fund patients in 2018.[9] OIG noted in its rescission opinion that the charity was not required to cease operations, but all relevant laws would apply to the charity's operations, and "any violations could trigger enforcement action."

Ultimately, OIG's advisory opinion rescission and the subsequent settlement are a reminder of established policy. This rescission was not triggered by a change in OIG's approach to patient assistance programs, but by a change in the facts the company had provided in obtaining the opinion. We recommend that companies adhere to representations they have made in interacting with the government. Patient assistance programs must have safeguards in place to prevent fraud and abuse—a manufacturer cannot use a third party to do what it lawfully cannot do on its own.

8 HHS OIG, Final Notice of Rescission of OIG Adv. Op. No. 06-04 (Nov. 28, 2017), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf.

9 Caring Voice Coalition, "A decision on 2018 financial assistance" (Jan. 4, 2018), http://www.caringvoice.org/decision-2018-financial-assistance.

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