

Patient Assistance Charity Sanctioned

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Last May, in [Patient Advocacy Nonprofits' Dark Ties to Industry](#), we highlighted the unfolding concerns by regulators about the unsavory ties between charities that advocate for disease sufferers and the pharmaceutical industry.

Many of these 501(c)(3) organizations take substantial money from for-profit health care interests, and the industry has seats on the boards of these groups. These conflicts of interest involve even powerhouse organizations like the American Diabetes Association.

There is increasing pressure to bring needed sunlight on these apparently problematic relationships.

Charity Ties to Drugmakers

In October, we updated this story in [Patient-Advocacy Charities' Dark Ties: Updates](#).

The Internal Revenue Service is now showing interest in a related issue, the unusually close ties between a patient-assistance charity and drugmakers that funds copayments and other financial help for disease sufferers who the charity helps and guides toward the drug-donors' medications.

One such group is the [Chronic Disease Fund](#); its tax exemption is under examination. For instance, in 2011, most of the almost \$130 million the group gave out in [co-payment support](#) was given to patients taking drugs made by the very companies that had donated that money to the 501(c)(3) organization. The IRS has also reportedly contacted drug giants Johnson & Johnson, Teva, Bayer AG, Biogen, and Novartis in connection with this probe.

New Charity Sanction by HHS

Just a few weeks later, news broke about [action taken](#) against another patient-assistance charity, the [Caring Voice Coalition](#), a 501(c)(3) organization, and a related investigation of a pharmaceutical

firm, United Therapeutics Corp., which makes pulmonary hypertension drugs. This time, though, instead of the IRS, the officials involved are from the Department of Health and Human Services, probing Medicare drug copayment irregularities.

More particularly, under federal law, pharmaceutical companies are not allowed to directly give copayment financial assistance to Medicare patients. That type of help would be considered an illegal kickback because it could direct the ill patients to one drug or another.

Under the rules, the drugmakers are allowed to donate to “independent” charities that are created to distribute patient assistance funds and services. In order to operate properly, the 501(c)(3) patient-assistance groups are authorized by the Office of the Inspector General (OIG) of HHS to act; the OIG gives the organization an “advisory opinion” to act as a drug reimburer.

In recent years, Caring Voice Coalition, based in Mechanicsville, Virginia, has been one of the nation’s largest patient assistance charities. Its stated purpose is to help patients afford costly medications by funding health insurance co-payments.

Regulators allege that, behind the scenes, the relationships between 501(c)(3)s like Caring Voice and big pharmaceutical firms were nefarious and conspiratorial. The drugmakers continually increased their donations to copay charities at the same time they were raising the price of the medications.

In late November 2017, the OIG’s office officially rescinded the authority of Caring Voice Coalition “for being in too close a relationship with its donors.” It is the first time the HHS Inspector General’s office has withdrawn a favorable advisory opinion. This first-of-its-kind rescission dates back to 2006.

The official letter specifically asserts that the 501(c)(3) “served as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient, and thus increased the risk that the patients who sought assistance ... would be steered to federally reimbursable drugs that the manufacturer donor sold.” In these situations, drugmakers have more ability to raise drug prices while “insulating patients from the immediate out-of-pocket effects of price increases, leaving Federal health care programs like Medicare (and the taxpayers...) to bear the cost.”

In the aftermath of this devastating move by HHS, Caring Voice Coalition may close down entirely. Financial records indicate the severity of this charity’s downfall: for the fiscal year ended 6/30/16, it had received nearly \$153.2 million in corporate contributions – a jump of \$20 million over the year before.

“The OIG’s move to rescind the advisory opinion comes amid a wide-ranging investigation by the Justice Department into the charities.” Also, Congress is getting into the act. Senator Ron Wyden (D-OR) characterized this practice as “of great concern” and requested more details on the nature of the interactions and which drug companies got the information.”

The drug firms are also being investigated. Recently, the Justice Department issued three subpoenas to Jazz Pharmaceuticals “related to its relationship with copay charities.” Celgene Corp., United Therapeutics Corp., Pfizer, and Gilead Sciences have also received federal subpoenas.

And, in another first, United Therapeutics Corp. has achieved its own “first” by settling a related case with the feds for \$210 million to resolve kickback allegations in a scheme to market a pulmonary arterial hypertension (PAH) medication through subsidies paid to charity and passed along to patients. Caring Voice Coalition was the partner named in this fraudulent plan.

Conclusion

These recent actions by federal authorities appear to be just the tip of the iceberg in connection with an ongoing – and expanding – probe into irregularities by any number of patient assistance charities and drugmakers. A list of pharmaceutical giants named by HHS relating to these patient-assistance charity schemes includes Johnson & Johnson, Pfizer, Astellas, Gilead Sciences, Celgene, Biogen, and others.

“A determination of whether any laws had been broken was beyond the scope of the advisory opinion process, the OIG said, though it added that ‘nothing in this letter limits the investigational or prosecutorial authority of OIG, the Department of Justice, or any other agency.’”

In a separate statement, the principal deputy assistant attorney general at DOJ’s civil division, Chad A. Reader, announced that this settlement “shows that the government will hold accountable drug companies that attempt to use illegal kickbacks”

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