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Charity Funded by Drugmakers Draws IRS Probe on Tax Exemption

By **Robert Langreth**

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- Government says Chronic Disease Fund was 'conduit' for donors
 - IRS seeks records from Roche, Biogen and other companies
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The U.S. Internal Revenue Service has opened a probe into the tax-exempt status of a charity funded by pharmaceutical companies, threatening a lifeline the industry uses to help patients buy expensive drugs for cancer, multiple sclerosis and other diseases.

The agency is exploring whether the [Chronic Disease Fund](#) [<https://www.bloomberg.com/quote/1026082D:US>](https://www.bloomberg.com/quote/1026082D:US), a patient-assistance charity funded largely by drugmakers, gave “impermissible” benefits to its corporate donors, according to federal court filings. An IRS analysis found that 95 percent of the \$129.3 million the charity spent on co-payment support in its public programs in 2011 went to patients taking drugs made by the very companies that had donated the money, according to court papers.

Donations from drug companies “are nearly all returned to those same pharmaceutical manufacturers as payments for the drugs they make,” attorneys for the IRS said in papers filed in federal courts in California, Pennsylvania and other states, seeking information related to the probe. “In effect, CDF is serving as a conduit for its pharmaceutical manufacturer ‘donors,’” government lawyers said.

The IRS has sent summonses to [Roche Holding AG](#) [<https://www.bloomberg.com/quote/RHHBY:US>](https://www.bloomberg.com/quote/RHHBY:US) s Genentech unit, [Biogen Inc.](#) [<https://www.bloomberg.com/quote/BIIB:US>](https://www.bloomberg.com/quote/BIIB:US), [Johnson & Johnson](#) [<https://www.bloomberg.com/quote/JNJ:US>](https://www.bloomberg.com/quote/JNJ:US), [Teva Pharmaceutical Industries Ltd.](#) [<https://www.bloomberg.com/quote/TEVA:US>](https://www.bloomberg.com/quote/TEVA:US), [Novartis AG](#) [<https://www.bloomberg.com/quote/NVS:US>](https://www.bloomberg.com/quote/NVS:US) and [Bayer AG](#) [<https://www.bloomberg.com/quote/BAYN:GY>](https://www.bloomberg.com/quote/BAYN:GY), seeking information on donations to CDF. Biogen, Novartis and Bayer said they’re cooperating with the IRS summonses, and Teva declined to comment. J&J said it has no control over how co-pay charities operate. Roche declined to comment on ongoing legal matters.

[Read More: How Big Pharma Uses Charity Programs to Cover Drug Price Hikes](#) [<https://www.bloomberg.com/news/articles/2016-05-19/the-real-reason-big-pharma-wants-to-help-pay-for-your-prescription>](https://www.bloomberg.com/news/articles/2016-05-19/the-real-reason-big-pharma-wants-to-help-pay-for-your-prescription)

Helping Patients

Drugmakers say their donations benefit society by helping patients pay for medicine that they wouldn't otherwise be able to afford. At the same time, a million-dollar contribution from a pharmaceutical company to a co-pay charity can potentially keep hundreds of patients from abandoning a costly drug, enabling the company donor to collect millions of dollars from Medicare.

The Chronic Disease Fund, according to a 2011 IRS analysis and a declaration by an IRS agent filed in court, set up narrow funds targeted at specific diseases. Many were largely funded by a single drug maker. Laws bar drugmakers from directly funding co-pays in Medicare. A lawyer for the charity said there's no requirement that a fund have multiple donors.

Donor Company	CDF Disease Fund	Amount CDF Spent on Assistance	Spent on Donor Company Drugs
Celgene	Multiple myeloma	\$42.6 million	98.4 percent
Genentech	Lung cancer	\$14.6 million	94.5 percent
Novartis	Iron overload	\$3.9 million	100 percent
Bayer	Liver cancer	\$3.7 million	100 percent

Source: IRS documents analyzing 2011 donations to CDF

Chronic Disease Fund, which is now called [Good Days](https://www.mygooddays.org/)

<https://www.mygooddays.org/>, said it has been told that the probe is an audit of its 2011 tax filings, its lawyer said in an email. In court filings, the Plano, Texas-based charity said its board is "fully independent" of its donors and that no company has the ability to select or influence the diseases or medicine

covered by its co-pay assistance program.

In 2013, a news report by Barron's suggested CDF was creating disease funds to help one of its donors. CDF later replaced its top executive and board of directors.

The IRS probe adds to the growing scrutiny of charities that help lower-income patients pay for expensive drugs. As prices have soared, pharmaceutical companies' contributions to patient-assistance charities have sparked accusations that the donations are, in effect, a profitable form of marketing subsidized by U.S. taxpayers. The seven biggest co-pay charities, which cover scores of diseases, reported combined contributions of \$1.1 billion in 2014 -- more than double their 2010 figures.

Kickback Rules

Strict anti-kickback rules prohibit pharmaceutical manufacturers from directly providing money to people enrolled in Medicare, the government health-care program for the elderly. Instead, they're permitted to donate to independent charities that help Medicare patients meet co-payments, provided the companies don't exert sway over how the nonprofits operate.

If an organization is no longer deemed a tax-exempt charity, drugmakers would probably stop donating to comply with federal regulations. That would jeopardize lucrative sales of expensive drugs to patients who need financial assistance.

Medicare enrollees who meet income guidelines can get much or all of their out-of-pocket drug costs covered by the charities: a large initial copay for a prescription, another sum known as the coverage gap or the donut hole, and more-modest ongoing costs. Under Medicare, a patient's co-pay for an expensive treatment can add up to thousands of dollars a year.

Separately, several drugmakers have recently received subpoenas [in-doj-probe-of-drugmaker-charity-connections](https://www.bloomberg.com/news/articles/2017-02-24/pfizer-subpoenaed-in-doj-probe-of-drugmaker-charity-connections) from the U.S. Attorney's office in Massachusetts about their relationships with patient-assistance charities, some related to Medicare co-payments.

"To the best of our knowledge, this tax audit is separate and unrelated to the subpoenas issued by the U.S. Attorney's Office in Massachusetts," said Lisa Keenan, a lawyer for Good Days.

The existence of the IRS probe was disclosed after the tax agency sent summonses to the six drugmakers, seeking information about their 2011 donations to CDF. Lawyers for the charity tried to get judges in four federal courts to halt the summonses, saying they were too broad. Government attorneys then laid out their position in court filings asking judges to deny CDF's petitions.

The agency "is investigating CDF's right to retain its tax-exempt status," lawyers for the IRS said in court papers.

'Conduit' Claim

The word "conduit" appears in several of the filings, suggesting the IRS is exploring whether "effectively this organization was serving as a marketing arm" for drug companies rather than a charity, said Marcus Owens

<http://www.loeb.com/attorney-marcussowens> , a former head of the tax-exempt division of the IRS and now an attorney in private practice. A spokesman for the IRS declined to comment, citing privacy laws.

Good Days, formerly CDF, “has always operated in accordance” with guidance issued by the Health and Human Services Department for such charities and “in no way acts as a ‘conduit’ for its pharmaceutical manufacturer donors,” Keenan, the charity’s lawyer, said in an email.

The charitable organization has provided more than \$1 billion in co-pay assistance to patients since 2003, which wouldn’t be possible without drug-company donations, Keenan said in a statement. A donation “in no way” influences which drug is prescribed, she said.

J&J said it has no control over how co-pay charities operate or “how much of their support to patients is directed for the use of our products.” Roche said it donates to multiple nonprofits that help patients with co-pays.

Disclosure Rules

The co-pay charities are prohibited by government regulations from disclosing detailed information about their operations because drug companies could use the data to calculate the impact on their bottom lines. The IRS analysis of CDF, while limited to just one year, reveals some of the most closely guarded secrets: which companies donated to the charity and where the money went.

In 19 of 24 disease-specific funds managed by the Chronic Disease Fund that received drug company funding in 2011, 90 percent of the spending ended up going to patients taking the primary donor companies’ drugs, according to an analysis by an IRS agent contained in court filings. The vast majority of the funds had just a single corporate donor, according to the IRS analysis.

Genentech, the biggest funder of CDF in 2011 according to the IRS analysis, donated more than \$70 million for at least nine disease funds that year. In seven of the disease funds Genentech supported, almost all the co-pay assistance ended up going to patients taking Genentech drugs, the IRS said.

Another big donor was [Celgene Corp.](https://www.bloomberg.com/quote/CELG:US) [<https://www.bloomberg.com/quote/CELG:US>](https://www.bloomberg.com/quote/CELG:US), which gave \$48.8 million in 2011 to support a fund for multiple myeloma patients, according to the IRS analysis. It was the only drug company donor to the fund and 98 percent of the money CDF spent in that fund went to patients taking drugs from Celgene, the IRS said. Celgene declined to comment.

— *With assistance by Benjamin Elgin, and David Voreacos*

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