United States Senate

WASHINGTON, DC 20510

December 4, 2019

Joanne Chiedi
Acting Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Chiedi:

We write today to express our ongoing concern about the misuse of independent charitable Patient Assistance Programs (PAPs), and to request that you revise guidance on the proper administration of these programs in light of recent enforcement actions. Currently, the perverse structure of these programs allows pharmaceutical companies to reap profits from their tax-deductible "charitable donations" while doing nothing to lower the high drug prices that force patients to rely on such programs in the first place.

PAPs provide financial support to patients through two different avenues: programs run directly by drug manufacturers that distribute drugs at no cost, and independent charities that help patients pay for their copays, premiums, and other out-of-pocket costs. As pharmaceutical companies continue raising their prices, many patients rely on PAPs to afford essential medications. Since 2001, both types of programs have expanded substantially. Contributions to PAP programs from the pharmaceutical industry have risen from $376 million in 2001 to $6.1 billion in 2014. These contributions now make up one-sixth of all corporate charitable deductions in the United States.[1]

Manufacturer-run PAPs cannot provide any cost-sharing assistance or coupons to Medicare beneficiaries, because providing these incentives would violate federal anti-kickback laws.[2] Independent charity PAPs, however, may provide co-payment or cost-sharing assistance to Medicare enrollees, as long as they operate with true independence from their manufacturer donors. As outlined in guidance issued by the Department of Health and Human Services Office of the Inspector General (HHS-OIG) in 2014, this means that donors cannot direct, guide, or steer charities in deciding which diseases or drugs are covered or how beneficiaries are chosen.[3] The guidance also pointed to two arrangements between donors and independent charity PAPs that would be subject to heightened scrutiny: disease-specific funds for beneficiaries affected by specific conditions, which should not be so narrowly defined that they result in "funding

---

[1] Congressional Research Service, "Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)," Suzanne Kirchoff, June 15, 2017, https://crsreports.congress.gov/product/pdf/R/R44264

[2] Specifically, Section 1128B (b) of the Social Security Act and the False Claims Act. *Id.*

[3] Department of Health and Human Services Office of the Inspector General, "Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs," May 30, 2014, https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf

exclusively or primarily" products manufactured by the fund's donors, and funds that limit their coverage to especially expensive or specialty drugs, rather than supporting all FDA-approved treatments for a given disease, which can increase costs to the health system overall by steering patients away from lower-cost therapies.

In the five years since this guidance was issued, mounting evidence indicates that pharmaceutical manufacturers have used purportedly "independent" charitable foundations to funnel taxpayer dollars into their own coffers, turning massive profits even while claiming tax deductions for their "donations." Specifically, since December 2017, the Department of Justice (DOJ) has reached settlements with at least eight pharmaceutical manufacturers, totaling more than $800 million, for funneling kickbacks through independent charity PAPs.[4] These included a $210 million settlement with United Therapeutics and a $360 million settlement with Actelion Pharmaceuticals, both for receiving kickbacks through a foundation that helped patients purchase the manufacturers' drugs for pulmonary arterial hypertension.[5]

In each of eight cases, the drug company worked with an "independent" foundation to set up a fund to which the company was the sole contributor. The fund was either directed to a specific condition that only the drug company's products were approved to treat, or funded only the specific kind of treatment the company manufactured. The fund was used to help patients purchase treatments with Medicare or other insurance benefits. In some cases, the donor company also received specific data from the foundation on how many of its products the fund had purchased, which showed that the revenue from the purchases far exceeded the initial donations.[6] As a result, at least one independent charity PAP, the Caring Voice Coalition, was forced to end its operations.[7]

---

[4] Department of Justice, "Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks," December 20, 2017, https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability; Department of Justice, "Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks," May 24, 2018, https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks; Department of Justice, "Drug Maker Actelion Agrees to Pay $360 Million to Resolve False Claims Act Liability for Paying Kickbacks," December 6, 2018, https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying; Department of Justice, "Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations," April 4, 2019, https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid; Department of Justice, "Two Pharmaceutical Companies Agree to Pay a Total of Nearly $125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations," April 25, 2019, https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid

[5] Department of Justice, "Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks," December 20, 2017, https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability; Department of Justice, "Drug Maker Actelion Agrees to Pay $360 Million to Resolve False Claims Act Liability for Paying Kickbacks," December 6, 2018, https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying

[6] Settlement Agreement between U.S. Department of Justice on behalf of HHS-OIG and United Therapeutics Corporation, pg. 2, December 19, 2017, https://www.justice.gov/usao-ma/press-release/file/1019336/download

[7] Department of Health and Human Services Office of the Inspector General letter to James C. Stansel re: Drug Companies that Provide Free Drugs to Federal Health Care Program Beneficiaries Impacting by Caring Voice Coalition, Inc.'s Decision Not to Provide Patient Assistance in 2018, January 4, 2018, https://oig.hhs.gov/compliance/alerts/guidance/stansel-letter.pdf

We applaud HHS-OIG for working with the DOJ to back up the 2014 guidance with aggressive enforcement actions. In light of these illegal schemes to cheat taxpayers, we urge HHS-OIG to reexamine its guidance about appropriate relationships between pharmaceutical industry donors and independent charity PAPs. While this crackdown has no doubt made pharmaceutical executives think twice about setting up narrow programs that directly funnel donations to their own products, there are a number of reasons to believe other arrangements may still result in corporate donors profiting directly from their ostensibly charitable contributions.

First, corporate donors may benefit from PAPs' lack of transparency. Most independent PAPs do not disclose which drugs are eligible for assistance. A recent study found that only two of the eight largest independent charity PAPs released public data on the drugs that were covered by their programs and their associated funding—and that data suggested PAP structures that benefited corporate donors at the expense of the healthcare system.[8] At those two PAPs, 59% of Medicare Part D drugs were not covered, and on average, covered drugs were three times as expensive as non-covered drugs.[9] Brand-name drugs were covered by an average of 3.1 PAPs, while their generic equivalents – which presumably are cheaper and offer more opportunity to put charitable dollars to good use - were inexplicably covered by an average of only 1.2 PAPs.[10] Drugs produced by a single manufacturer were more likely to be covered than drugs produced by multiple manufacturers.[11] This study suggests that PAP programs may be violating HHS-OIG guidance by failing to cover all FDA-approved treatments. Although patients may need more help affording more expensive drugs, covering only higher-cost treatments can also have the effect of steering patients away from lower-cost options, benefiting drug manufacturers at the expense of taxpayers. With little transparency, it is impossible for patients, the public, and HHS-OIG to know whether drug assistance decisions correlate with donors' interests and whether PAPs are complying with HHS-OIG guidance.

In addition, PAPs appear to be targeting patients who have health insurance—a strategy that ensures a revenue stream for drug companies and limits access to care for a patient population in need of financial assistance. The same recent review of independent PAPs found that 97% of programs required patients to have health insurance in order to qualify for financial assistance.[12] While targeting assistance to insured patients could allow foundations to spread their limited funds over the largest number of recipients, it also guarantees that their largest donors, pharmaceutical manufacturers, will receive a payment from insurers for each grant that they provide. A grant that helps an insured patient meet a co-pay has the result of leveraging the donation to secure the insurer's full negotiated rate for the drug. This results in a savings for the patient – but allows the manufacturer to ultimately receive full payment and imposes significantly higher costs on the healthcare system.

---

[8] JAMA, "Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs," So-Yeon Kang, Aditi Sen, Ge Bai, and Gerard Anderson, August 2019, https://jhu.pure.elsevier.com/en/publications/financial-eligibility-criteria-and-medication-coverage-for-indepe

[9] *Id.*, pg. 425

[10] *Id.*, pg. 426

[11] *Id.*, pg. 425

[12] *Id.*, pg. 422

Furthermore, evidence also suggests that drug manufacturers, even if they do not dominate the market for a particular drug or treatment, may still profit off of their donations to independent PAPs. Tax experts have concluded that, even in a scenario where a manufacturer produces a drug that holds 25% of the market share, contributions to a charitable foundation could result in enough revenue to produce a profit margin of 60% - a profit "earned" at the expense of taxpayers and ratepayers.[13]

There is no doubt that many patients benefit from the financial assistance provided by PAPs. However, given the widespread kickbacks uncovered by recent HHS-OIG investigations, the troubling characteristics of the largest programs, and the appearance of manufacturers' profiteering, the time has come to tighten HHS's oversight of charitable PAPs to ensure that they prioritize the needs of patients over those of their pharmaceutical company donors. HHS-OIG should update its guidance for independent charity PAPs to:

- Require independent charity PAPs to publicly disclose which treatments they cover and provide written justifications for any deviations from the FDA's full list of approved treatments for any specific disease or condition.
- Require all PAPs to cover generic alternatives to brand-name treatments whenever available.
- Prohibit independent charity PAPs from excluding potential beneficiaries on the basis of their insurance status.
- Prohibit pharmaceutical company donors from earmarking their donations for disease-specific funds, regardless of how narrowly the funds are defined.
- Require annual public reports from each PAP on applicant characteristics, approval rates, insurance status and type for both applicants and participants, distribution of spending, and data shared with donors.

When pharmaceutical companies are criticized for high drug prices that put their products out of reach for patients, they often point to their charitable contributions to PAPs.[14] But even as these donations provide cover for untenably high drug costs, they are also turning a profit for the drug manufacturers themselves, enabling ongoing price gouging, and failing to use charitable funds to treat the neediest patients at the lowest cost. It is past time to end this inside game and ensure that public charities are serving patients and their families, rather than steering kickbacks to deep-pocketed pharmaceutical companies at taxpayer expense.

---

[13] For example, consider a scenario where a pharmaceutical manufacturer produces a drug that holds 25% of the market share, averages 8 treatments per patient, and bills $1000 to the insurer for each treatment, with a $125 co-pay from the patient. The manufacturer donates $10 million to an independent charity PAP, which is enough to help 8,000 patients afford their treatments (subtracting some cost for overhead). Two thousand of these patients use the assistance to purchase the manufacturer's drug. The manufacturer would receive revenue of $8,000 for each of the 2,000 patients, for a total of $16 million in revenue from their $10 million donation – a profit margin of 60%. *Tax Notes,* "The Cloak of Social Responsibility: Pharmaceutical Corporate Charity," Austin Frerick, November 28, 2016, https://www.researchgate.net/profile/Austin_Frerick/publication/312084333_The_Cloak_of_Social_Responsibility_Pharmaceutical_Corporate_Charity/links/586e56ae08ae8fce491b6b01/The-Cloak-of-Social-Responsibility-Pharmaceutical-Corporate-Charity.pdf

[14] Testimony of Olivier Brandicourt, M.D., Chief Executive Officer, Sanofi, before the Senate Committee on Finance, February 26, 2019, https://www.finance.senate.gov/imo/media/doc/26FEB2019BRANDICOURT-SANOFI.pdf

We ask that you update your guidance as rapidly as possible, and provide our offices with a staff-level briefing no later than December 20, 2019 to provide an update on your oversight of independent PAPs.

Thank you for your consideration.

Sincerely,

Elizabeth Warren
United States Senator

Sheldon Whitehouse
United States Senator