

# Independent Charitable Copay Foundation Donations

## What to Consider and Steps to Take Before Donating and What Recent Court Challenges Might Mean for Industry

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### Independent Charity Copay Foundations

- A number of independent, *bona fide* charitable copay foundations provide financial assistance to help patients, including Medicare Part D beneficiaries, afford their medications
- Foundations develop funds based on disease areas
- No AKS safe harbor, but OIG has said (2005 Special Advisory Bulletin SAB)) that manufacturers can donate to these funds so long as:
  - Charity not too narrowly defined (no single product fund)
  - Charity does not limit assistance to high-cost specialty drugs
  - Manufacturer does not have direct or indirect influence or control over the charity or the fund
  - Charity awards assistance in an independent manner that severs any link between manufacturer's funding and the beneficiary
  - Charity awards assistance without regard to manufacturer's interests and without regard to beneficiary's choice of product or HCP
  - Manufacturer does not solicit or receive data from the charity that would facilitate correlating the amount or frequency of donations with the number of subsidized prescriptions for its products

### OIG: Supplemental PAP SAB (2014)

- May 2014: OIG re-emphasized the need for independence between donors and charities
  - Narrowly tailored disease funds that cover few products, or that apply differing eligibility criteria, benefit designs, or off-label policies for certain funds but not others, will be scrutinized closely to determine if the fund structures are for the benefit of a particular donor or otherwise serve as a conduit between a manufacturer and patients
  - Specialty therapeutic funds are worth watching

- Key is for fund to be defined consistent with “widely recognized clinical standards” and “in a manner that covers a broad spectrum of available drugs”

## ICPAP Settlements

- Manufacturer settlements to date include:  
Actelion, Aegerion, Alexion, Amgen, Astellas, Celgene, Gilead, Jazz, Lundbeck, Novartis, Pfizer, Sanofi, United Therapeutics
- Foundation settlements include:  
Chronic Disease Fund (aka Good Days), Patient Access Network, Patient Services, Inc., The Assistance Fund

## Common ICPAP CIA Terms

- Policies, procedures, training regarding arrangements and interactions with Independent Charity PAPs
  - Comply with the AKS and FCA
  - Comply with OIG 2005, 2014 SABs
- Establish Independent Charity Group for ICPAP matters completely separate from commercial personnel (e.g., sales/marketing)
  - No commercial role, influence over review, approval, donation decisions
  - No commercial communication with or receiving information from PAPs
- Establish an annual budget based on objective criteria, in consultation with Legal and Compliance (no commercial role)
- Establish standard criteria/contractual terms; use written agreements
  - No involvement, influence over ICPAP in any manner
  - No donations to single product funds, funds only cover company products
- CIAs cover traditional areas as well (e.g., RAMP, promotion, disclosure log, training, etc.)
- Several CIAs go beyond donations to ICPAPs and include:
  - Grants and charitable donations to any third party; and

- A manufacturer's operation of, or participation in, any "patient assistance program" by the company or an entity acting on its behalf
  - "patient assistance program" not always defined or explained
- Pfizer CIA includes:
  - Free product to patients (also in United Therapeutics)
  - "programs to provide financial assistance to patients in the form of cost-sharing assistance (i.e., co-pay coupons or co-pay cards)"
- PAP Review Program
  - Monitor 10 or 50% (whichever greater) of company donations to ICPAPs
    - Risk-based and random sample approach
    - Review budget, donation documents, correspondence/emails, etc.
- Independent Review Program (IRO) review of ICPAPs, CIA

## Compliance Takeaways

- It is important to consider the current PAP environment and trends when structuring patient assistance programs and ICPAP donations
- Exercise care with char
- itable donation budgeting and decision-making
- Conduct due diligence on charities, disease funds
  - Funds too narrowly defined? Does charity have current OIG AO?
  - Consider prohibiting donations to funds that are: (1) single product; or (2) only company products
- Do not interfere with charity independence
  - Do not seek to define, influence fund definition, eligibility criteria, charity website or advertising
- No commercial personnel involvement with charities
  - Ensure proper firewalls are in place between company personnel responsible for patient assistance programs vs. ICPAP donations
- Seek robust representations and warranties regarding independence and compliance in donation agreements
- Limit information exchanges, communications with charity

- No improper coordination, sharing of patient data
- Be careful about references to PAPs, donations in pricing documents
- Do not conduct ROI on charity donations
- Do not advertise company donations to HCPs, patients, or public
- All company personnel should be prohibited from “promoting” charity funds or referring to charities in any medium (oral, web, print)
  - Funds are not a service or promotional tool for selling, comparing products
- Hubs or call centers should only provide limited, factual information about charities (e.g., website with list of all funds in alphabetical order)
  - Hub should not fill out any charity paperwork for patients, HCPs
  - Hub may provide limited information about status of fund (e.g., open, closed)
- Establish robust policies, procedures, and training regarding ICPAP donations and patient assistance programs
- Conduct oversight, monitoring of ICPAP donations and patient assistance programs to ensure compliance with company rules and applicable laws

### **Industry Challenges to Charitable Foundation Prosecutions and OIG Compliance Guidance**

- Pfizer
  - Declaratory Judgment Action brought by Pfizer on June 26, 2020 against the United States Department of Health and Human Services, Secretary Azar, the OIG and its Principal Deputy Inspector General Christi Grimm
    - Asserts that the prohibition on manufacturer copay assistance (directly and through Foundations) to Medicare patients violates the First (free speech) and Fifth (due process; equal protection) Amendments to the United States Constitution

### **Industry Challenges to Charitable Foundation Prosecutions and OIG Compliance Guidance**

- First Amendment Challenge
  - Prohibition on its copay assistance programs infringes Pfizer’s First Amendment right to engage in speech incident to charitable giving and imposes impermissible speaker-based restrictions on Pfizer as a pharmaceutical manufacturer
- Fifth Amendment Challenge

- Prohibition on copay assistance programs discriminates on the basis of wealth without being rationally related to a legitimate government interest
- Keep in mind that the proposed copay assistance programs relate to only two of Pfizer's products and not their entire portfolio
  - The only FDA approved treatments for a rare, progressive, fatal heart condition
  - Alternative treatments include organ transplants and off-label prescribing of drugs not approved to treat the heart condition
- Recently, the DOJ filed suit against Regeneron (June 24<sup>th</sup>) and Teva (August 18<sup>th</sup>) related to their donations to charitable foundations
  - Suggestive that both companies are pushing back against the DOJ and not settling as other companies have done
- Notably
  - DOJ's press release in the Regeneron matter highlights ROI calculations allegedly used by the company when deciding on donation amounts
  - DOJ's press release in the Teva matter highlights price increases on Copaxone "at a rate over 19 times the rate of inflation" (329% increase) and the undermining of Medicare's copay structure "which Congress created as a safeguard against inflated drug prices"

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