

Compliance, Reporting, and Enforcement in Charity Patient Assistance Programs

James G. Sheehan, Chief

Charities Bureau

Office of New York Attorney General Tish James

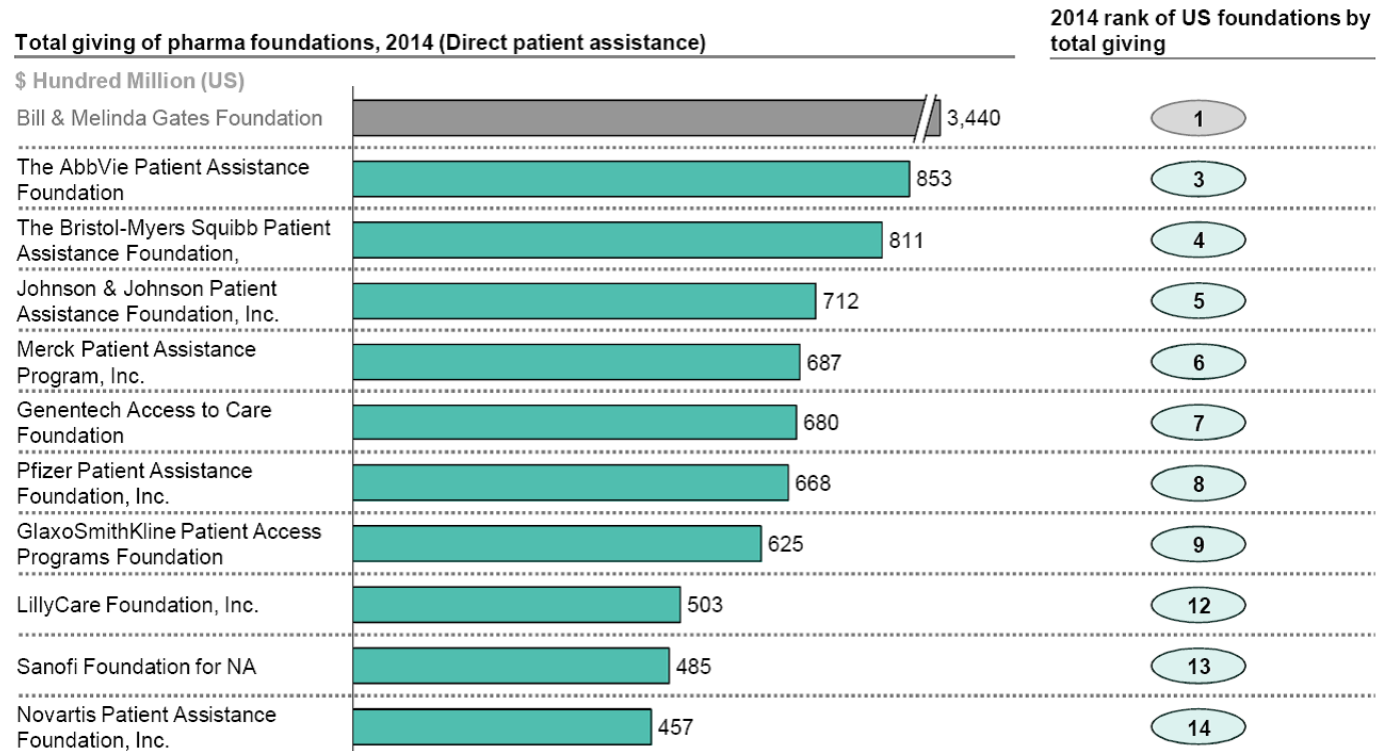
James.Sheehan@AG.NY.gov

NEW YORK ATTORNEY GENERAL
LETITIA JAMES



PATIENT ASSISTANCE PROGRAMS

EXHIBIT 2: **Top pharma patient assistance foundations and relative ranking in total giving**



Source: The Foundation Center

Patient Assistance Programs

- inability to afford medications is especially for older adults, a cause for nonadherence to medication regimens
- Efforts to address this inability:
 - Financial assistance to patients
 - Free prescription drugs for patients
 - Free-standing charities
 - Charities programs run by companies or their contractors(e.g., Amgen Safety Net Foundation)
- Commercial vendors with monthly charges to recipients (e.g., Rx Assistance Programs-<https://rxassistanceprograms.com>)

Independent Patient Assistance Program Charities

- Financial assistance to patients
- Free prescription drugs for patients
- OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees 70 FR 70623 (11/22/05) (pre-Part D)
- OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs 79 FR 70623 (5/30/2014)
- OIG Advisory Opinion 07-18 (2007) to Patient Access Network Foundation (PANF)
- Modified 2011 (PANF)
- Modified 2015 (PANF)

Supplemental Special Advisory Bulletin (2014)

- Risks:
- Narrowly defined therapeutic class
- Coverage only for “expensive” or specialty drugs
- Limits to subset of available drugs
- Best practices:
- Reasonable, verifiable, uniform measure of financial need
- Consistent application
- Limitation on reports to donors
 - Number of applicants
 - Number of qualifiers
 - Aggregate amount disbursed
 - No data to correlate contributions with recipients who use its products

BASIC QUESTIONS

- Complexity-financial assistance ok for all programs except for “any federal, state, or local program such as Medicare or Medicaid.”
- Assistance ok for Medicare Part D patients who have spent \$1000 on prescription medicine in the current calendar year?
- Can physicians complete forms, gather evidence, and advocate to charity for coverage for their patients?
- Can donors provide software to prescribing physicians to help them advocate for or access financial assistance for their patients?
- Can physicians enlist the assistance of sales or marketing reps, or other donor employees, for advice or information on applying for financial assistance?
- NONE OF THESE ISSUES DISCUSSED in the 2014 Supplemental Special Advisory Bulletin

PATIENT ACCESS NETWORK FOUNDATION ("PANF")-IN ITS OWN WORDS

- “Independent, national 501 (c)(3) organization dedicated to providing underinsured patients with financial assistance”
- “Close to 70 disease-specific funds that provide access to progressive therapies.”
- “ Since 2004, PANF has provided nearly 1 million underinsured patients with over \$3 billion in financial assistance to cover out-of-pocket expenses for their prescribed treatments.”

CHRONIC DISEASE FUND DBA GOOD DAYS ("CDF") IN ITS OWN WORDS

- \$245 million distributed in 2017; 118,712 patients received assistance
- “We assist patients who meet income qualifications guidelines and have private insurance or a Medicare Part D Plan but cannot approve their co-payments for their FDA-approved drugs.”

The Charities Laws

- Public filing and disclosure through IRS 990, state filings (CharitiesNYS.com)
- “Private inurement” state and federal doctrine
- 501(c)(3) organizations
- No part of the net earnings of such organizations may inure to the benefit of any private shareholder or individual
- Primary focus-compensation, transactions with charity assets, loans to officers, credit cards, severance payments
- How applicable to patient assistance charities?
- Donor may donate restricted funds for specific purpose-charity accepting such funds must use for designated purpose

Patient Assistance Settlements with Pharmaceutical Companies

- December 2017-**United Therapeutics** \$210 million settlement
- May 2018-
 - **Jazz Pharmaceuticals**-\$57 million
 - **Pfizer** \$23.85 million settlement
 - DOJ allegation-improper use of PAN to pay out of pocket costs for Medicare patients (described as kickback)
 - AAG of DOJ-"kickbacks undermine the independence of physicians and patient decision-making, and raise health care costs."
 - DOJ: Pfizer worked with Advanced Care Scripts to move patients taking kidney cancer drugs to the Foundation rather than providing free drugs
 - Fund established at PAN for patients taking Tikosyn-allegedly coordinated with price hike
 - Five year CIA

Patient Assistance Settlements with Pharmaceutical Companies

- April 2019 **Amgen-\$24.75 million**

THE LATEST NEWS - 10/23/2019 - PANF; CHRONIC DISEASE FUND (“CDF”) in OIG/DOJ’s words

- PANF Settlement Agreement with DOJ-\$4 million settlement
- CDF Settlement Agreement with DOJ-\$2 million
- Corporate Integrity Agreements with HHS/OIG
- “CDF and PANF functioned not as independent charities, but as pass-throughs for specific pharmaceutical companies to pay kickbacks to Medicare patients taking their drugs.” US Attorney Andrew Lelling, DMass.

WHAT OIG Corporate Integrity Agreements Require of Donor Assistance Charities

- Standard Compliance Officer and Program
- Covers interactions with third parties (vendors, hubs, pharmacies) as well as donors
- “PANF shall operate with absolute, independent, and autonomous discretion as to the establishment of disease funds and the use of Donor contributions.”
- “PANF . . . Shall determine the diseases it supports through its funds.”
- Standardized independent internal process for establishment of disease funds.
- “Widely recognized clinical standards . . . Broad spectrum of products.”

WHAT OIG Corporate Integrity Agreements Require of Donor Assistance Charities

- No limit to high cost or specialty drugs
- Records of all internal and external communications “about any and all decisions relating to the Disease Fund Process”
- “PANF shall not establish, delineate, or modify a disease fund at request of Donors”
- No provision of data related to donor products/Data Sharing policies
- No request for specific donation amounts for any Donor for a fund/no earmark for specific drug or disease state within a given fund.
- No consideration of identity of any of patient’s health care providers in determining eligibility for patient assistance
- Written standards for screening process for patient eligibility

WHAT OIG Corporate Integrity Agreements Require of Donors

- From 2019 Amgen agreement:
- Standard Compliance Officer and Program
- Policies and procedures to address “arrangements and interactions with . . . Independent Charity PAPS”
- Materials that may be distributed by Donor personnel and manner in which personnel may respond to requests for information
- Creation of a PAP Governance Committee independent from “Amgen’s commercial organization”
- PAP Governance Committee has sole responsibility for communicating with Independent Charity PAPS
- Amgen’s commercial organization shall not communicate with, influence, or be involved in any communications with or receive information from PAPS.

WHAT OIG Corporate Integrity Agreements Require of Donors to Independent Charity PAPs

- PAP Governance Committee shall develop an annual budget for donations based on objective criteria in accordance with general guidelines approved by the legal department
- “Amgen shall approve the annual budget for donations to Independent Charity PAPs through a process or organization that does not include, nor is influenced by, the commercial organization (e.g., the Amgen Finance Department)”
- “the budget to be used for donations shall not be based on monies allocated to the PAP Governance Committee from the commercial organization.”
- Strict criteria for independence of Charity PAP-(pp. 19-20)

The Future of Independent Patient Assistance Charities

- Patients with Private Insurance Coverage
- What about IPA Charities holding Restricted Funds?
- The Charities Development/Donation Process-“the ask”
- Contact with physicians
- Managing calls from reps and executives
- Monitoring and Auditing
- Dealing with “private patient advocates”

**Thank You for Your Attention
and the Work You Do**

James Sheehan

NYAG – Charities Bureau

<http://www.charitiesnys.com>

James.Sheehan@ag.ny.gov