

## A dialogue with ChatGPT

I am going to ask you for help in drafting a policy on pharmaceutical companies providing funding to an independent co-pay foundation. Before you do so, can you provide a list of risks that companies should be aware of?

### ChatGPT said:

When pharmaceutical companies provide funding to independent co-pay foundations (ICPFs), they must be mindful of a range of legal, regulatory, reputational, and operational risks. Below is a detailed list of these risks:

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#### 1. Regulatory and Compliance Risks

##### a. Anti-Kickback Statute (AKS) Violations

Pharmaceutical companies may be at risk of violating the federal Anti-Kickback Statute if funding to a foundation is used to induce or reward the prescribing of specific drugs. This is especially true if the company is found to influence how funds are allocated or if support is restricted to their own products.

##### b. False Claims Act (FCA) Exposure

Improper donations could lead to allegations that companies are causing false claims to be submitted to federal health care programs, particularly if the funding enables patients to use drugs covered by Medicare or Medicaid that they would not otherwise afford.

##### c. Office of Inspector General (OIG) Scrutiny

The OIG provides guidance on appropriate interactions with co-pay foundations, and deviation from this guidance can trigger investigations or sanctions. For instance, earmarking funds for specific diseases tied closely to the donor's product portfolio can be problematic.

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#### 2. Reputational Risk

##### a. Public Perception of Influence

There is significant risk if it appears that the pharmaceutical company is indirectly steering patients toward their products by funding disease-specific programs. This may erode public trust and attract media or advocacy group criticism.

### **b. Media and Legislative Scrutiny**

Media outlets and lawmakers often scrutinize patient assistance programs, and any perceived manipulation can result in negative press, hearings, or new regulatory initiatives.

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## **3. Legal Liability and Enforcement Actions**

### **a. Civil Settlements and Penalties**

Numerous pharmaceutical companies have paid substantial fines (often in the tens or hundreds of millions) to resolve allegations tied to improper donations to co-pay foundations.

### **b. Corporate Integrity Agreements (CIAs)**

Settlements with the U.S. government can result in CIAs that impose extensive compliance obligations on companies, including mandatory audits and reporting.

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## **4. Operational and Compliance Challenges**

### **a. Oversight of Donations**

Companies must ensure proper internal controls and documentation of all funding decisions, rationale, and interactions with foundations. This includes firewalls between commercial teams and those making donation decisions.

### **b. Transparency and Reporting**

Some jurisdictions require transparency reporting (e.g., Sunshine Act), and while co-pay donations may not always be directly reportable, lack of transparency can create issues if later scrutinized.

### **c. Selection of Disease Funds**

If disease funds are defined narrowly and align too closely with a single product, this may be interpreted as an attempt to funnel funds inappropriately.

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## **5. Foundation Independence Risk**

### **a. Risk of De Facto Control**

Any effort to influence foundation operations, such as suggesting which patients should be supported or how funds are distributed, jeopardizes the foundation's independent status and creates legal exposure.

## **b. Conflict of Interest Concerns**

If foundation leadership or decision-makers have any ties to the pharmaceutical company, this can raise concerns about objectivity and independence.

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Would you like help incorporating controls and safeguards to mitigate these risks in the policy draft?

### **You said:**

Can you provide information on recent settlements related to co-pay foundation funding so I can brush up on the topic. What were the key findings from these settlements? •

### **ChatGPT said:**

Recent settlements involving pharmaceutical companies and co-pay assistance foundations have underscored significant legal and compliance risks. These cases primarily center on violations of the Anti-Kickback Statute (AKS) and the False Claims Act (FCA), where companies allegedly used charitable donations to improperly subsidize Medicare patients' co-pays, thereby promoting their own drugs. Below is a summary of notable settlements and their key findings:[Reuters+1](#)[Reuters+1](#)

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## **1. Teva Pharmaceuticals – \$450 Million Settlement (2024)**

- **Allegations:** Teva was accused of donating over \$350 million to two co-pay foundations between 2006 and 2017 to cover Medicare patients' co-pays for its multiple sclerosis drug, Copaxone. This practice allegedly served as a kickback to boost drug sales.[Benesch Law+2](#)[Reuters+2](#)[Reuters+2](#)
  - **Outcome:** Teva agreed to pay \$425 million to resolve these allegations, marking the largest co-pay assistance settlement to date. An additional \$25 million was paid to settle related price-fixing claims. [Powder & Bulk Solids+2](#)[ArentFox Schiff+2](#)[Department of Justice+2](#)
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## **2. Biogen – \$22 Million Settlement (2020)**

- **Allegations:** Biogen allegedly used two foundations as conduits to pay Medicare co-pays for patients taking its multiple sclerosis drugs, Avonex and Tysabri, violating the

AKS and FCA. [ArentFox Schiff+10Office of Inspector General+10Department of Justice+10](#)

- **Outcome:** The company paid \$22 million to resolve these allegations. [Office of Inspector General+5Office of Inspector General+5Department of Justice+5](#)
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### 3. Jazz Pharmaceuticals, Lundbeck, and Alexion – Combined \$122.6 Million Settlement (2019)

- **Allegations:** Each company was accused of using co-pay foundations to pay Medicare or Civilian Health and Medical Program (ChampVA) co-pays for their own products, effectively using the foundations as conduits for kickbacks. [Department of Justice+8Office of Inspector General+8Office of Inspector General+8](#)
  - **Outcome:** The companies collectively agreed to pay over \$122 million to resolve these allegations. [Office of Inspector General](#)
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### 4. Astellas Pharma and Amgen – Combined \$124.75 Million Settlement (2019)

- **Allegations:** Both companies were accused of illegally paying Medicare co-pays for their own products through purportedly independent foundations, violating the FCA. [Office of Inspector General+3Department of Justice+3Office of Inspector General+3](#)
  - **Outcome:** Astellas and Amgen agreed to pay a total of nearly \$125 million to settle these claims. [Department of Justice+1Office of Inspector General+1](#)
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### 5. Incyte Corporation – \$12.6 Million Settlement (2021)

- **Allegations:** Incyte allegedly used a foundation as a conduit to pay the co-pays of Medicare and TRICARE patients taking its drug Jakafi, violating the AKS and FCA. [Reuters+10U.S. Department of Defense+10Department of Justice+10](#)
  - **Outcome:** The company agreed to pay \$12.6 million to resolve these allegations. [Covington & Burling+9U.S. Department of Defense+9Department of Justice+9](#)
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## Key Takeaways from These Settlements

- **Use of Foundations as Conduits:** Pharmaceutical companies must ensure that donations to co-pay assistance foundations are not used to directly or indirectly subsidize co-pays for their own products, as this can be construed as a kickback.[The Anti-Fraud Coalition+1Department of Justice+1](#)
- **Compliance with AKS and FCA:** Violations of the AKS and FCA can result in substantial financial penalties and reputational damage. Companies must implement robust compliance programs to mitigate these risks.
- **Foundation Independence:** Maintaining a clear separation between pharmaceutical companies and co-pay assistance foundations is crucial. Any influence over the foundation's operations or fund allocations can lead to legal scrutiny.

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If you need assistance in drafting a policy to ensure compliance with these regulations and to mitigate associated risks, feel free to ask.

### You said:

What changes did pharmaceutical companies make based on these enforcement actions?  
What do enforcement agencies expect?

### ChatGPT said:

Based on enforcement actions related to co-pay foundation funding, pharmaceutical companies have implemented a range of **compliance reforms and operational changes** to mitigate legal risk and align with regulatory expectations. These changes are driven by **guidance from the U.S. Department of Justice (DOJ), Office of Inspector General (OIG), and Health and Human Services (HHS)** to prevent Anti-Kickback Statute (AKS) and False Claims Act (FCA) violations.

Below is a summary of:

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## 1. Changes Pharmaceutical Companies Made After Enforcement Actions

### A. Strengthening Compliance Frameworks

- **Firewalls Between Commercial and Compliance Functions**  
Companies have created strict separations between commercial teams and those involved in charitable donation decisions to prevent commercial influence on which disease funds or foundations receive money.
- **Independent Review Committees**  
Many companies now utilize cross-functional or external committees to approve co-pay donations, ensuring decisions are based on objective need rather than commercial benefit.
- **Enhanced Policies and SOPs**  
Policies now more clearly define permissible donation practices, prohibit earmarking funds for specific products, and ensure donations are consistent with OIG guidance.

## **B. Donation Governance and Documentation**

- **Standardized Due Diligence Processes**  
Prior to approving donations, companies conduct detailed diligence on the foundation's governance, independence, financial practices, and history of compliance.
- **Detailed Recordkeeping and Rationale**  
Firms document all donation decisions, including how the need was assessed and how the donation meets defined criteria unrelated to commercial priorities.
- **Auditing and Monitoring Programs**  
Internal audits now assess compliance with donation policies, foundation communications, and adherence to established firewalls.

## **C. Communication Restrictions**

- **No Communication About Product-Specific Use**  
Companies prohibit discussions with foundations about particular products or expected utilization.
  - **Avoidance of Disease Fund Narrowing**  
Companies have broadened disease categories in donations to avoid targeting funds that would predominantly benefit one of their own drugs.
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## **2. What Enforcement Agencies Expect**

The DOJ and OIG have made their expectations clear through Corporate Integrity Agreements (CIAs), advisory opinions, and public statements. Key expectations include:

### **A. Foundation Independence**

- **No Influence on Fund Operations**  
Companies must not influence how foundations select patients, design disease funds, or allocate resources.
- **No Solicitation of Patient Data or Reimbursement Info**  
Enforcement agencies prohibit any quid pro quo arrangements involving data sharing between the company and the foundation.

### **B. Avoidance of Product-Specific Support**

- **No Narrow Disease Definitions**  
Funds should be defined by broad disease states, not tied to conditions primarily treated by a company's drug.
- **No Conditioning or Steering**  
Companies cannot encourage physicians or patients to use foundations in a way that favors their drug.

### **C. Transparency and Controls**

- **Establishment of Formal Policies**  
Companies must maintain written procedures that govern donations, oversight, and internal controls.
- **Training and Reporting Requirements**  
Employees involved in the donation process should receive compliance training. Any suspected violations must be reported and investigated.
- **Proactive Self-Disclosure**  
Agencies encourage companies to proactively disclose any potential issues rather than waiting for investigations.

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## **3. Corporate Integrity Agreement (CIA) Provisions**

Settlements often lead to CIAs that require:

- **Annual Reports to the OIG**
  - **Independent Compliance Expert Reviews**
  - **Board-level Compliance Oversight**
  - **Third-party Audits**
  - **Implementation of Risk Mitigation Plans**
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If you're preparing to draft a policy, I can help you outline key elements that reflect these industry practices and enforcement expectations. Would you like a policy template or example language based on these principles?

### **You said:**

Can you help me write a policy in clear, easy-to-understand language that addresses these specific risks?

### **ChatGPT said:**

Certainly! Below is a **clear, easy-to-understand policy** that addresses the specific risks pharmaceutical companies face when providing funding to independent co-pay foundations. This version is designed for internal use and can be adapted for compliance manuals, SOPs, or training materials.

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## **Policy on Donations to Independent Co-Pay Foundations**

### **Purpose**

This policy ensures that any donations made by [Company Name] to independent co-pay assistance foundations are conducted in a legal, ethical, and compliant manner. The goal is to support patient access to treatment **without influencing prescribing decisions or violating healthcare laws**.

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### **Scope**

This policy applies to all employees, contractors, and departments involved in charitable donations, patient assistance programs, legal, compliance, and commercial functions.



## Policy Statement

[Company Name] may provide financial support to independent, bona fide co-pay assistance foundations to help patients afford their out-of-pocket healthcare expenses. These donations must be:

- **Independent of any commercial interests**
  - **Not linked to any specific product or therapy**
  - **Consistent with federal and state laws**, including the Anti-Kickback Statute (AKS) and False Claims Act (FCA)
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## Key Principles and Requirements

### 1. No Product-Specific Support

- Donations must never be tied to the use, promotion, or volume of any specific drug or product sold by [Company Name].
- Disease funds should be broadly defined (e.g., “cancer” or “multiple sclerosis”) and **must not mirror the indication of a single product.**

### 2. Foundation Independence

- [Company Name] must not:
  - Influence how foundations operate or how patients are selected.
  - Request or expect data on which patients use [Company Name] products.
  - Suggest or require that a foundation create or maintain specific disease funds.

### 3. Separation from Commercial Influence

- Employees in commercial, marketing, or sales roles **must not be involved** in decisions about co-pay donations.
- All funding decisions will be made by the Compliance, Legal, or Corporate Affairs teams based on **objective criteria**, such as public health need.

#### 4. Due Diligence and Documentation

- Prior to funding, the foundation must be vetted for:
  - Legal and tax-exempt status (e.g., IRS 501(c)(3))
  - History of compliance with OIG guidance
  - Policies ensuring independence from donors
- All decisions must be:
  - Documented with a clear, non-commercial rationale
  - Reviewed and approved through a formal internal process

#### 5. Monitoring and Auditing

- [Company Name] will conduct **regular audits** of its donation activities to ensure adherence to this policy.
- All donations will be tracked in a central log maintained by Compliance or Legal.
- Foundations receiving donations may be required to certify annually that they operate independently.

#### 6. Communication Restrictions

- No communications with foundations about:
  - Specific patients
  - How donations will be used
  - Expected volume of product usage
- [Company Name] may only receive publicly available information or general impact summaries.

#### 7. Transparency

- Donation recipients and amounts may be publicly disclosed as appropriate.
  - Any concerns or suspected violations must be reported immediately to the Compliance Department or through the company's anonymous hotline.
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### **Training**

All employees involved in the donation process must complete annual training on this policy and applicable laws.

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### **Enforcement**

Violations of this policy may result in disciplinary action, up to and including termination. The company may also report violations to regulatory authorities as required by law.