Patient Assistance Programs and Co-Pay Cards

Hot Topics, Recent Enforcement, and Unpredictable Politics

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Explanatory Notes

• All the information discussed is based on publicly available information

• None of the information we share today reflects non-public or “inside” information

• Some of the information discussed today is based on DOJ, OIG, and Congressional statements, and related materials

• Caution is appropriate with respect to whether these statements provide a complete, accurate, and/or fair depiction of the conduct of any company or individual

• Compliance suggestions: requires individualized assessment
Discussion Topics

I. Overview of PAPs and Patient Assistance

II. PAPs Under Fire & In the Spotlight

III. Risk Management Strategies & Legal Defenses

IV. Post-Election Considerations
“The gentleman at the other register would like to cover your co-pay.”
Patient Assistance: PAPs

- Patient assistance in the form of free product or reimbursements for co-pays or deductibles for indigent patients or patients who cannot otherwise afford their medication
  - Focus on uninsured or underinsured patients who cannot afford their medication

- Two types of PAPs:
  - Manufacturer-run PAPs
  - Third-party charity PAPs often funded by manufacturer donations/grants
Patient Assistance: Co-Pay Cards and Coupon Programs

• Any form of direct support offered by manufacturers to insured patients to reduce or eliminate out-of-pocket expenses for prescription drugs

• Common forms of support: coupons (print or electronic), debit cards, direct reimbursements

• Usually offered without regard to ability to pay

• Most manufacturers exclude federal (and some state health care) program beneficiaries
2005: “Patient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs”

2014: “We recognize that copayment support may benefit beneficiaries by encouraging adherence to medication regimes, particularly when copayments are so high as to be unaffordable to many patients”
But Natural Tension — Commercial vs. Charity

- Co-pay programs and PAPs generally commercially-driven
  - Developed, supported, and funded by sales and marketing
  - One purpose is to sell product, gain market share, encourage patient loyalty

- Co-pay programs and particularly PAPs are intended to expand access to patients and help patients afford expensive life-saving products
  - Often involve charitable donations
  - Patient ability to pay a key factor
  - Address unmet patient needs
Natural Tension — Legal Implications

- While the charitable/beneficial component of the programs are recognized and encouraged, the commercial aspects of these programs create legal risk:
  - Potential for illegal inducement to beneficiaries under the federal Anti-Kickback Statute (AKS) or similar state laws
  - Potential for illegal inducements to prescribing physicians
  - Possible tortious interference with private payor-patient contacts
  - Appearance of anti-competitive, exclusionary conduct that violates federal antitrust laws
Take two pills every four hours until the end of time. Side effects: your doctor may experience kickbacks.
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PAPs in the Spotlight — Old News?

How Big Pharma Uses Charity Programs to Cover for Drug Price Hikes
May 29, 2016
A billion-dollar system in which charitable giving is profitable.

Drug Coupons: Helping a Few at the Expense of Everyone
Margot Sanger-Katz @sangerkatz
The New York Times
OCT. 12, 2016

Feds Probe Drugmaker-Charity Connections
May 27, 2016

Why Big Pharma’s patient-assistance programs are a sham
Los Angeles Times
September 25, 2015
Regeneron gets wrapped up in federal patient assistance investigation

Dialysis Chains Receive Subpoenas Related to Premium Assistance

DOJ Keeps the Spotlight on Patient-Assistance Charities: Is This CSR?
PAPs Under Fire — Congress Steps Into the Fray
Mr. Shkreli goes to Washington...

Martin Shkreli (Turing); Michael Pearson, Howard Schiller, Bill Ackman (Valeant/Pershing); Heather Bresch (Mylan)
The tip of the iceberg is making us look bad.

It gives extortion a bad name!

We may be unethical, greedy and cynical and all.

But at least we're nice and legal.
February 8, 2017

Mr. Spencer Williamson
President and Chief Executive Officer
Kaléo Pharmaceuticals
111 Virginia Street, Suite 300
Richmond, VA 23219

Dear Mr. Williamson:

We are deeply concerned about reports that Kaléo dramatically increased the cost of its naloxone injection device, Evzio, an FDA approved medication used for the emergency treatment of an opioid overdose—from $690 for a two pack in 2014 to $4,500 today. This drug is now in the hands of first responders and families struggling with substance use disorder across the country. It is particularly needed in rural areas where access to life-saving emergency services can be limited. Such a steep rise in the cost of this drug threatens to price-out families and communities that depend on naloxone to save lives.

How many devices does Kaléo set aside for your donation program compared to your total production and how are you ensuring that it meets the demand for devices among first responders, state health departments, and other public health entities across the country? Please explain what steps Kaléo has taken to inform consumers of their eligibility for these donation programs.

To help us understand Kaléo’s actions, we would appreciate your response to the following:

1. Please detail your pricing structure for Evzio since the product received FDA approval and provide documentation for why the company has chosen to adjust the pricing structure, including information on if the production costs of Evzio contribute to the price increases.

Please provide details of the financial assistance programs available for low-income patients.

March 3, 2017

Mr. Jeffrey S. Aroniin
Chairman and CEO
Marathon Pharmaceuticals, LLC
1033 Skokie Blvd.
Northbrook, IL 60062

Dear Mr. Aroniin:

We wrote to understand the pricing scheme for Marathon's recently approved product Emflaza, the non-proprietary name deflazocort. Deflazocort, like prednisone, is a steroid and is internationally used to treat the symptoms of Duchenne Muscular Dystrophy (DMD). DMD is a rare genetic disorder that affects approximately 1 in 3,500 male births in the U.S., and most boys do not live past their teens and 20s. The circumstances of the development of Emflaza, the benefits that will accrue to Marathon as a new drug, raise serious questions about whether there is any way to keep the drug's price from being dramatically high.

Like many steroids, has numerous medical applications. However, no company has approval of this drug until Marathon's own drug application (NDA) filing. In 2016, some companies have been importing deflazocort from Canada and Europe at about $100 per generic use. Last month, the FDA approved the approval of NDA for deflazocort FDA approval of Marathon's NDA, Marathon announced that it planned to charge $89,000 a year for the drug—a price 50- to 70-times more expensive than the price in Europe.
“Mylan estimates that ‘as many as 8 million Americans’ have food allergies that could trigger life-threatening anaphylactic shock. From September 2015 through September 2016, however, your Patient Assistance Program provided only 3,042 EpiPen 2-Paks to only 2,965 customers. It defies logic that of the 8 million Americans that need EpiPens, only 3,000 meet the Eligibility requirements for the Patient Assistance Program. . . . What steps will Mylan take to increase utilization of its Patient Assistance Program?”

“This is the same PR playbook other companies use. When your price increases finally spark public outrage, just say you’re expanding your patient assistance programs and make as much money as you can along the way.” Rep. Elijah Cummings
DOJ Investigating PAPs

Biogen under investigation for patient-assistance programs

Express Scripts gets subpoenas over drug company, pharmacy ties

Valeant subpoenaed over patient assistance program, pricing

Horizon Pharma shares fall on govt subpoena news

Celgene Accused of Using Charities ‘Scheme’ to Gain Billions

Gilead Subpoenaed as Feds Probe Drugmaker-Charity Connections

Jazz Pharmaceuticals Discloses DOJ Subpoena on Patient Assistance Program
DOJ Kicking the Tires re: OIG Guidance & Pricing

• “Where a manufacturer PAP offers subsidies tied to the use of the manufacturer’s products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries’ incentives to locate and use less expensive, equally effective drugs.” 2005 OIG SAB

• “These opinions do not address actions by donors to correlate their funding of PAPs with support for their own products. Such actions may be indicative of a donor’s intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute. 2014 OIG SAB

• DOJ also investigating the effect of PAP programs on pharmaceutical pricing
DOJ & Congress Aligned
“The great thing about self-medicating is there is a low co-pay
OIG: Renewed Scrutiny on PAPs

- Nov. 7, 2005, OIG Issues Special Advisory Bulletin on Charitable PAPs
- May 21, 2014, OIG Issues Supplemental SAB in response to NYT, Seeking Alpha, etc.
- Reiterates positions from 2005 SAB, but narrows it
- Takes positions that are more stringent than existing OIG Advisory Opinions
- Limits the way charitable disease funds can be structured to limit channeling of Pharma donations to their own products or patients
Key Differences Between 2005 and 2014 SABs

• The foundation must not function as a conduit for payments by the manufacturer and must not impermissibly influence beneficiaries’ drug choices

• Foundations may not artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of a donor’s products

• Disease funds may not be defined by reference to specific symptoms, severity of symptoms, disease stages, method of administration, or any other way of narrowing the definition of widely recognized disease states

• OIG is unlikely to approve any disease fund that covers only one drug

• Patient assistance must be available for all products, including generic or bioequivalent drugs, covered by Medicare when prescribed for the treatment of the disease states covered by the fund
Key OIG Developments and Post 2014 SAB Actions

• Simultaneous with the issuance of the 2014 SAB, OIG started re-evaluating charitable foundations that had previously received favorable OIG Advisory Opinions.

• OIG required new certifications aligned with the updated 2014 SAB requirements to continue operating under a favorable Advisory Opinion.

• OIG has indicated that its primary concerns and focus are on both the manufacturers that provide the donations, as well as the foundations that administer them.
PAPs Drawing Academic Attention — A Mixed Bag

“More rigorous research is needed to establish the clinical and cost-effectiveness of PAPs from a patient and healthcare perspective.”

PAPs “are not as good as they seem,” and “if we rely on copay assistance, it just drives prices up in the long run.”
The Horse is Out of the Barn . . .
... But Some Limited Positive Attention

Notes sense of compassion undergirding PAPs, and explaining the complex interaction between manufacturers and PBMs and that “PBMs write the rules of the road”

Bloomberg’s “reporting is, as the movie disclaimer goes: ‘inspired by a true story’”
“Your Prescription is $30, but there’s a $75 co-pay
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Keys for Compliance — Charitable Foundations

• Have an independent, bona fide charitable organization interposed between the manufacturer and patients in a manner that effectively insulates beneficiary decision-making from information attributing funding or benefit to any manufacturer.

• The independent charity should have:
  — Truly independent Board or Directors
  — No conflicts of interest
  — Adequate structure to ensure no donor control over the organization
  — Policies to ensure (1) consistent measure of financial need, and (2) no data will be shared with donors that could allow correlation between donation and use of donor’s products

• Charity must be without influence, and donor should not create appearance of influence.
Keys for Compliance — Co-payment Programs

- Review coupon program structure and administration to ensure compliance with OIG 2014 guidance

- Goal: ensure that federal beneficiaries meet co-payment obligations

- Safeguards to consider:
  - More prominent notices to beneficiaries and pharmacies
  - Maintaining consistent eligibility questions across all coupon formats and preventing circumvention
  - Obtaining certifications from beneficiaries/pharmacists that recipient is not a federal healthcare program beneficiary
  - Evaluate effectiveness of claims edits process in pharmacy claims transaction
Compliance Conclusions and Common Threads

- Broad public concerns about patients being able to afford the cost of their medications
- Broad public and private concerns about various forms of assistance being used to push patients toward higher cost medications
- The media, Wall St., and the government are watching closely
- There is a rebuttable presumption that the patient assistance is permissible
  - Patient assistance should be divorced from sales/marketing
  - All forms of assistance must adhere to federal healthcare program requirements
  - Internal (and external) communications and structures should align to the above
Legal Issues — Kickback Theories Tested

* * *

There is no doubt that this case is distasteful; it may be worse than that. But our concern is not with tawdry tales of Ferraris, Rolexes, and ball gowns. It is instead with the broader legal implications of the Government’s boundless interpretation of the federal bribery statute. A more limited interpretation of the term “official act” leaves ample room for prosecuting corruption, while comporting with the text of the statute and the precedent of this Court.

The judgment of the Court of Appeals is vacated, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.
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Market Pummeled, but Biotech Soars

Pharma Stocks Are Soaring After Donald Trump's Victory

Trump win boosts drug stocks as prospect of price curbs recedes
“You folks have done a terrific job over the years, but we have to get prices down for a lot of reasons.” (January 31, 2017)

“The U.S. drug companies have produced extraordinary results for our country, but the pricing has been astronomical for our country.” (January 31, 2017)

“Pharma has a lot of lobbies, a lot of lobbyists and a lot of power.” (January 11, 2017)
Administration Turnover

Attorney General Loretta Lynch

Deputy Attorney General Sally Yates

Secretary of Health and Human Services Sylvia Mathews Burwell

Attorney General Jeff Sessions

Deputy Attorney General Rod Rosenstein

Secretary of Health and Human Services Tom Price
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DISCUSSION & QUESTIONS