



PATIENT SUPPORT PROGRAMS: RISK AND RISK MANAGEMENT BEST PRACTICES

November 7, 2018

19th Annual Pharmaceutical and
Medical Device Compliance
Congress

NAVIGANT

Agenda

Introductions

Setting the Stage: Relevant Laws and Guidance

Definitions Matter

Risks & Best Practices for Management

Questions & Discussion

Introductions: Your Panel

Ann Beasley (Moderator)

Jennifer Chillas

Nereyda Garcia

Casey Horton

Keith Korenchuk

Nicole Serena

GETTING TO KNOW THE AUDIENCE

Questions for the Audience (show of hands)

What size companies are represented in the audience?

- Pre-approval
- 1-product
- More than one-product
- Multi-national company

Individual backgrounds

- Legal
- Compliance
- Commercial
- Medical Affairs
- Other

OVERVIEW OF LEGAL
LANDSCAPE, ENFORCEMENT
AND INDUSTRY CODES

Guidance Related to PSPs/PAPs in the US

- There has been increased government scrutiny in the US surrounding PSPs/PAPS over the past few years
 - *In November 2017, the OIG made the decision to rescind an advisory opinion it had previously issued to the charity, Caring Voice Coalition, in 2006, which protected Caring Voice Coalition from liability under the Anti-Kickback Statute for its work providing Medicare patients with premium and cost-sharing assistance.*
 - *Caring Voice Coalitions interactions with United Therapeutics contributed to United Therapeutics entering into a five year CIA with the OIG*
- Currently, there is limited industry guidance on PSPs/PAPs in the US despite being a high risk activity that can be associated with violating a variety of federal laws and regulations, including:
 - anti-kickback statutes,
 - False Claims Act
 - HIPAA patient-privacy violations
- Companies should look to guidance from recent CIAs related to PAPs, as well as industry guidance on PAPs/PSPs from other countries to determine whether enhancements and improvements are required to mitigate compliance risk in programs

Media Now Focusing on Nursing Allegations

DJIA **26701.72** 0.17% ▲ Nasdaq **8037.82** 0.12% ▲ U.S. 10 Yr **-1/32 Yield 3.070%** ▼ Crude Oil **70.77** -0.49% ▼ Euro **1.1743** -0.31% ▼

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What's News

Drugmakers' Free Services Trigger Anti-Kickback Probe

Federal prosecutors are probing whether big drugmakers including Sanofi, Gilead Sciences and Biogen potentially violated laws by providing free services to doctors and patients.



Workers from Maximo Solar Industries install solar panels at a residence in Bayamón, Puerto Rico, earlier this month.

Kavanaugh's Accuser Open to

Markets

	U.S.	EUROPE	ASIA	FX	RATES	FUTURES
DJIA	26701.72				44.74	0.17%
S&P 500	2937.00				6.25	0.21%
Nasdaq	8037.47				9.24	0.12%
Russell 2000	1723.06				2.87	0.17%
DJ Total Mkt	30454.86				64.25	0.21%

Sep 21 '18, 10:00 AM EDT

Recent Cases: Nursing Support, Value-Added Services*

	Company	Settlement	Conduct
1	Bayer/Amgen (E.D. Tx.)	Ongoing (DOJ declined)(Betaseron/Nexavar)	Support services, nurses
2	Gilead (E.D. Tx.)	Ongoing (DOJ declined)(Hep C/HIV)	Support services, nurses
3	Eli Lilly (E.D. Tx.)	Ongoing (DOJ declined)(Humalog, Humulin, Forteo)	Support services, nurses
4	UCB (S.D. Ill.)	Ongoing (DOJ declined)(Cimzia)	Support services, nurses
5	Biogen (D. Mass.)	Ongoing (DOJ declined)(MS drug)	Support services, nurses
6	Amgen (E.D.Pa.)	Ongoing (DOJ declined)(Enbrel, Repatha, et al.)	Support services, nurses
7	EMD Serono/Pfizer (E.D.Pa.)	Ongoing (DOJ declined)(MS drug)	Support services, nurses
8	AbbVie (CA/N.D. Ill.)	CA intervened; (DOJ declined)(Humira)	Support services, nurses
9	Gilead (CA)	CA (Alameda Cty. Subpoena)	Support services, nurses
10	Gilead (E.D.Pa.)	Subpoena (Solvadi/Harvoni)	Support services, nurses
11	Teva (E.D.Pa.)	Ongoing (DOJ declined)(MS drug)	Support services, nurses
12	AstraZeneca (W.D.Wa.)	Ongoing (DOJ declined)(several drugs)	Support services, nurses
13	Sanofi (SDNY)	CID (diabetes products)	Support services, CDEs
14	Lundbeck/Otsuka (N.D. Ill.)	Ongoing (DOJ declined)(Abilify)	Support services, nurses

Nursing Support Best Practices

- Nurse education programs should be consistent with “limited support” guidance from OIG. Consider:
 - Ensuring nurses do not receive incentive compensation
 - Training nurses separately from sales representatives
 - Limiting or restricting nurse use of branded materials -- per below, must be transparent that nurse is compensated by the drug company and must be PRC approved
 - Creating separation between branded and unbranded nurse communications
 - Bringing nurses in-house, rather than contracting with vendors
- Nurses should not discuss other Company patient support
 - For example, nurses should not discuss Hub support or patient assistance programs
 - Questions about other support activities should be referred to the Company or to Hub representatives
- Adopt controls to mitigate risk that HCPs could bill for nurse education programs subsidized by Company
- Disease education/awareness materials should not be tied to company products
- All nurse communications should be transparent as to Company’s support of the program
 - Nurses should not conceal the fact that they work for the Company and that they are not to provide independent medical judgment or interact with patients to support care
- No Company representatives should market the spread or provide consulting advice to physicians on profitability
 - Do not, for example, permit nurses to discuss practice management time, E/M encounters, or administrative support in managing patients

Nursing Support Best Practices (continued)

- Best practice is for nurse education not to occur in the HCP's office. Should be at patient's home or in independent location/call center
- Sales representative communications about nurse programs or hub programs should be limited, high-level, and purely factual
 - For example, sales representatives (or any field representative) should not cite nurse or hub programs as a differentiator or a reason to prescribe
 - Avoid “value” words in promotional communications, such as “benefit, “for your office,” will “save you time,” “concierge,” “white glove” or “comprehensive”
- Hub support should be limited -- perform a BI and providing information or blank forms concerning PA's and appeals. Company and representatives should not fill out clinical parts of forms
- Field roles should refer patient specific questions to the Hub or to FRM (if one exists), but even FRMs should not use hub support programs or nurses as product differentiator. FRMs should not promote product or be incentive compensated
- Billing and coding guides should: (a) include a complete list of on-label codes; and (b) disclaim that any code will guarantee coverage and state that drug company is not providing clinical or treatment advice
- Recommend against nurse programs for oral products
- Any PAPs need to be for full calendar year, not for partial years or until alternative coverage can be found
- Post-prescribing decision nurse programs should be reviewed against prudential factors, considering patient safety benefits of having nurse oversight of patient injection process and/or side effect management
- All treatment related decisions and roles should be referred to the prescribing physician. Nurses should not engage in diagnosis or treatment

Co-Pay Foundations: Enforcement

- Currently aggressive enforcement of manufacturer donations to copay foundations
- The following companies have been subject to subpoenas, enforcement:

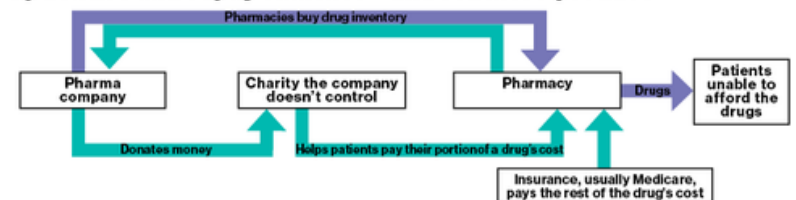
- | | |
|--|---|
| 1. Valeant (Oct. 2015) (SDNY) | 11. Pfizer (May 2018 \$24M settlement & CIA) (D. Mass.) |
| 2. Patient Access Network (PAN) (subpoena in Nov. 2015) | 12. J&J (Feb. 2017) (D. Mass) |
| 3. Celgene (Jul. 2017 \$280M Settlement) (D. Mass.) | 13. United Therapeutics (Jul. 2017 \$210M Settlement and CIA) (D. Mass.) |
| 4. Horizon Pharma. (Feb. 2016) (SDNY) | 14. Astellas (Nov. 2017)(D. Mass.) |
| 5. Gilead Sciences, Inc. (May 2016) (D. Mass.) | 15. Chronic Disease Fund (CDF) / Good Days (~2015) (IRS) |
| 6. Jazz. Pharm. (\$57M Settlement announced May 2018) (D. Mass.) | 16. Sanofi (D. Mass.) |
| 7. Biogen Inc. (May 2016) (D. Mass.) | 17. Aegerion Pharm. (Jan. 2018 \$35M settlement, DPA, CIA) |
| 8. Lundbeck (\$52.6M Settlement announced Jun. 2018) | |
| 9. Alexion Pharm. (Dec. 2016) (D. Mass.) | |
| 10. Regeneron (Feb. 2017) (D. Mass.) | |



Option 1: Give away the drugs (it's called "compassionate product")



Option 2: Fund copay charities—and sell more product



GRAPHIC BY BLOOMBERG BUSINESSWEEK; DATA: COMPILED BY BLOOMBERG

Why is DOJ Looking at Copay Foundations?

DOJ Theories: The Little Picture

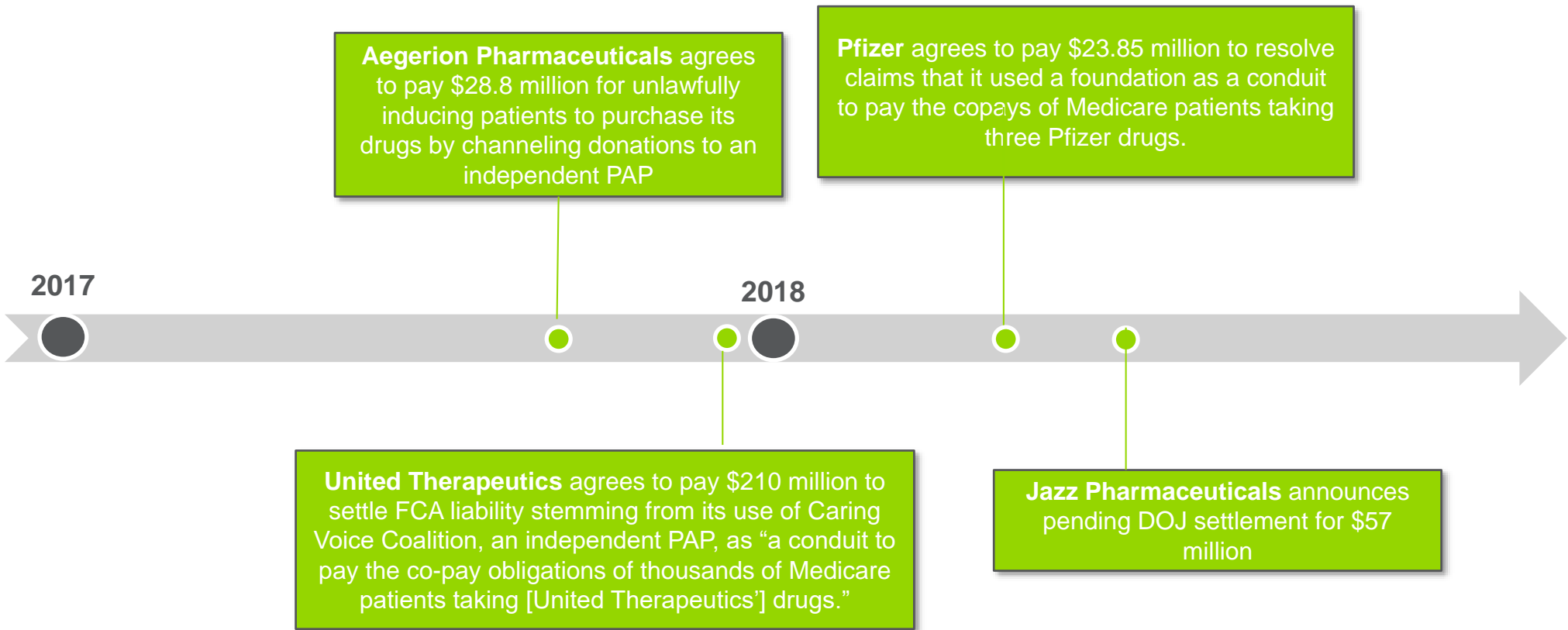
- Narrowly defined disease states
- Lack of independence between charities and donors
- Cost sharing subsidies ultimately limit providers' collection risks

DOJ Theories: The Big Picture

- “Enabler” relationship between donations and drug pricing decisions
- Treating donations as charitable deductions even though for commercial purpose
- Foundations as mechanism to steer prescriptions
- Subsidies constitute discounts to plans in that they allow plans to shift costs to consumers

CIA ACTIVITY RELATING TO
PATIENT SUPPORT PROGRAMS
& PATIENT ASSISTANCE
PROGRAMS

CIA Enforcement



Case Study: United Therapeutics



- **December 20, 2017:** United Therapeutics entered into \$210 million settlement with USAO-MA
- First ever settlement agreement related solely to Charity PAP
- United is alleged to have funneled funds through a Charity PAP – Caring Voice Coalition (“CVC”) – to help pay out-of-pocket costs on prescriptions for four of its pulmonary arterial hypertension drugs
- Specific allegations:
 - Obtained correlation data from CVC and used it to conduct an ROI analysis
 - Prohibited Medicare patients from participating in its free drug program; instead referred them to CVC
- As a result, entered into a five-year CIA with OIG
- Terms contained within the CIA:
 - **Establishment of Charity Group Separate and Independent from Commercial**
 - Sole responsibility over Charity PAP donations and activities sits in a group or team (the Independent Charity Group) that operates independently from Commercial
 - **Independence and Objectivity of the Donation Process**
 - The Independent Charity Group must:
 - Establish a budgetary process independent from Commercial interests
 - Establish an annual budget based on objective criteria in accordance with guidelines approved by Legal
 - Donations to Charity PAPs and disease funds must be guided by standardized, objective written criteria
 - **Review / Audit of the Donations Program and Process**
 - Must periodically evaluate:
 - Budget documents
 - Documents relating to any decision to provide donations to a particular independent Charity PAP
 - Written agreements with Charity PAPs
 - Correspondence and other documents reflecting interactions between United and the Charity PAP

Lessons Learned: CIA Key Principles



Separate PAP/PSP activities from Commercial



Ensure the independence of the donation and budgeting process from commercial considerations, and establish objective criteria governing the donation process





















Implement data sharing restrictions to ensure the company cannot correlate the amount or frequency of its donations with support for its products or related services






Conduct monitoring and auditing of charitable donation programs / arrangements

PSP GUIDANCE FROM OTHER COUNTRIES

International Guidance Related to PSPs

	 ABPI Guidance	 Canadian Code	 Australian Code
Definition of PSP included?			
Guidance is pharmacovigilance-focused?			
Includes requirements for designing a compliant PSP?			
Includes information on handling data?			
Includes information on AE reporting?			

International Definitions of PSPs

	Guidance Document	Definition
	ABPI: Guidance Notes for Patient Safety and Pharmacovigilance in Patient Support Programmes (2011)	A service for direct patient or patient carer interaction/engagement designed to help management of medication and/or disease outcomes (e.g. adherence, awareness and education), or to provide healthcare professionals (HCPs) with support for their patients
	Innovative Medicines Canada: Code of Ethical Practices Section 14 (2016)	Patient Support Programs are programs offered by Member companies for the benefit of patients. The programs aim at increasing or facilitating patient understanding of a disease and / or treatment, better patient outcomes as well as possibly improving patient adherence to treatment. Such programs may also serve to ensure or assist with access and/ or reimbursement of a product. The programs must have a primary objective of bettering patient health outcomes. Any benefit experienced by the prescribing or dispensing Health Care Professional must be incidental to the primary objective
	Medicines Australia: Code of Conduct Section 17 (2015)	A Patient Support Program is a company developed program that is intended to assist patients in gaining benefit from their medical treatment and to improve health outcomes and promote the quality use of medicines. Patient Support Programs may only be offered to patients who have already been prescribed a prescription-only Product.



ABPI Guidance Notes for Patient Safety and Pharmacovigilance in Patient Support Programmes (2011)

- Scope of the guidance is ‘intended to help companies address the PV obligations and regulatory authority expectations related to PSPs’
- Defines PSPs as ‘*a service for direct patient or patient carer interaction/engagement designed to help management of medication and/or disease outcomes (e.g. adherence, awareness and education), or to provide healthcare professionals (HCPs) with support for their patients.*’
- Suggested PV elements for documenting in PSPs
 - Objective of the PSP and needs defined by each stakeholder group
 - PSP Design
 - PSP Description (incl. Operational Details, Handling Customer Interactions, Safety Data Handling, and Patient Materials)
 - Systems and Data Requirements
 - Data Protection

6e. Summary of report handling in PSPs

- Reporting Handling in PSPs

Report type	Seriousness	Requirement for:		
		HCP confirmation attempts	Causality assessment*	Signal detection**
Spontaneous/ stimulated	Serious	Yes	No	Yes
	Non-serious	Yes	No	Yes
Solicited	Serious	Yes	Yes	Yes
	Non-serious	Yes	Yes	Yes



ABPI Guidance Notes for Patient Safety and Pharmacovigilance in Patient Support Programmes (2011)

- Adverse Event Training
 - All those involved in running a PSP should undergo training on product information and AE training to support recognition of AEs and ensure appropriate and timely reporting of AEs to the MAH.
 - It is particularly important when the PSP is outsourced that the MAH should ensure it has systems in place to monitor compliance of the outsourced provider.
- Outsourcing
 - If a third party is identified to run the PSP on behalf of the MAH, it should undergo detailed assessment (due diligence) by the MAH to determine whether it has the capabilities, processes and personnel in place to enable it to run the programme
 - PV and safety data exchange provisions should be defined in the contract between the MAH and the third party.
- Signal Detection
 - Data from PSPs should be identifiable in the safety database such that signal detection may be carried out separately on the specific set of data, in order to avoid detection of false positive signals



Innovative Medicines Canada Code of Ethical Practice

Section 14 – Patient Support Programs and Medical Practice Activities

- 14.1 – Definitions
 - Patient Support Programs are programs offered by Member companies for the benefit of patients. The programs aim at increasing or facilitating patient understanding of a disease and / or treatment, better patient outcomes as well as possibly improving patient adherence to treatment.

- 14.2 – General Principals
 - Intent
 - *These programs / services must not serve solely to cover day to day activities or resources considered part of the practice's operational expenses nor should they replace or compete with services or resources provided and funded by the existing healthcare system. Effort should be made for the healthcare system to absorb the cost of long term initiatives.*
 - Ensure Integrity of the Industry
 - Conflict of Interest
 - Design and Oversight

- 14.3 – Standards
 - Patient Support Programs or Medical Practice Activities must have clear objectives, timelines and scope
 - Reasonable efforts should be made to ensure Patient Confidentiality, Transparency and Privacy
 - Data and Outcomes

- 14.4 – Request for Support by Stakeholders



Medicines Australia Code of Conduct

Section 17 - Patient Support Programs

- A PSP is a company developed program that is intended to assist patients in gaining benefit from their medical treatment and to improve health outcomes and promote the quality use of medicines.
- PSPs may only be offered to patients who have already been prescribed a prescription-only Product.
- PSPs should be conducted in an open and transparent manner
 - Any payments made to healthcare professionals for facilitating, enrolling or educating patients in a Patient Support Program must be declared to consumers on the enrolment form.
- Information provided to patients may be product specific but not promotional
- There must be:
 - a clinical rationale for the PSP
 - anticipated number of patients to be enrolled in the program
 - the type of educational/informational material to be provided to a patient
 - contact if any (for example phone calls, SMS, email), that may be made to a patient and the duration of the program.
- Companies must ensure compliance with requirements listed in this section
- Data and Outcomes
- Suspected Adverse Drug Reactions noted during monitoring of a Patient Support Program must be reported to the TGA in accordance with the current TGA document Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines (August 2013).

Section 2.5 - Prescribing Software

- A company may pay for the inclusion of medical education for healthcare professionals or patient aids, patient support program registration and patient aids and patient support program materials in a prescribing software package.

DEFINITIONS MATTER

- Definitions Matter:
 - What are we talking about?
 - What are our business colleagues talking about?
 - Is it the same?

- What are the most common manifestations or structures of Patient Support Programs?

- What are the risks associated with these common activities?

RISKS &
BEST PRACTICES FOR
MANAGEMENT

- What are you doing differently for each?
 - Donations to Charitable CoPay Foundations
 - Nurse Educators
 - Patient Ambassadors / Mentors
 - Reimbursement HUBs
 - Fee Product

QUESTIONS & DISCUSSION