Life sciences reimbursement disputes

Advisory

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Life science organizations face substantial risk of reimbursement related disputes, and even with recent declines the resulting penalties remain very high. These disputes are often accompanied by a flood of related civil and criminal lawsuits from other stakeholders against not only the company, but also its individual managers, directors, and officers.

Government and commercial payers continue to allege Anti-Kickback Statute (AKS) and False Claims Act (FCA) damages for increasingly varied matters related to pricing, marketing, and product strategies. The scope of the allegations is no longer limited to big pharmaceutical manufacturers as all payers are now pursuing matters against smaller pharmaceutical, biotech, medical device companies, as well as large insurers and private plan administrators.

The magnitude of this issue is staggering as government and commercial payers continue to devote extensive time, money, and resources toward these matters. In recent years, there has also been an explosion of activity at the state level for reasons including activities of the National Association of Medicaid Fraud Control Units (NAMFCU) and the addition of individual state FCA.

The potential impacts are well-known within the industry. Allegations alone can damage reputations and adversely impact the overall political environment. Defense of these lawsuits can be a long and arduous process that distracts research teams and management from core objectives while pressuring financial performance.

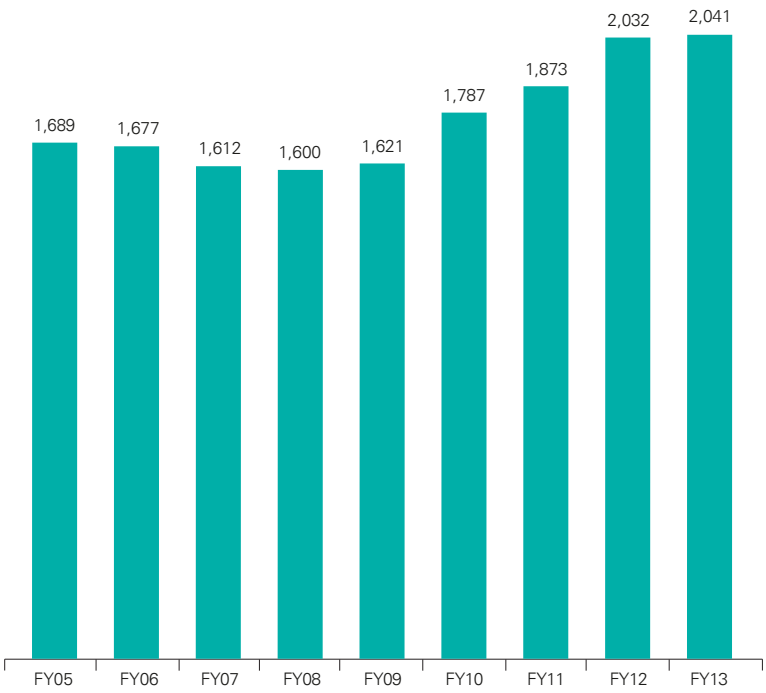
Manufacturers and their counsel should engage assistance from professionals who are experienced in these matters, who understand industry operations, payments, and related data, and who also offer a broad array of coordinated services and support. When faced with an actual complaint, it is important to involve these resources at the outset as their perspective can be critical to early case strategy and discovery matters.

The DOJ is also targeting smaller companies. According to U.S. Attorneys, "The companies that are next on the list, are small and medium sized companies"[1]

> *"Although in the short term certain cases against individuals may not provide as robust a monetary return on the Department's investment, pursuing individual actions in civil corporate matters will result in significant long-term deterrence." (Yates, 2015)*[2]

> *"Government payers include, but are not limited to, federal programs such as Medicaid, Medicare, VA, PHS/340B and TRICARE as well as state specific programs.*

Pending Criminal Investigations



Source: HHS/DOJ Annual Reports – Health Care Fraud and Abuse Control Program, FY 2005 – FY 2014 [4]

"Absent extraordinary circumstances or approved departmental policy, **the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation." (Yates, 2015)[3]**

"In order to qualify for any cooperation credit, corporations must provide to the Department all relevant facts relating to the individuals responsible for the misconduct." (Yates, 2015)[5]

Government enforcement actions against life science companies continue with a heavy emphasis on kickback allegations. Select recent enforcement actions:[6]

Manufacturer	Settlement Amount	Year	Alleged Conduct
Novartis	$390 million	2015	Kickbacks
Warner Chilcott	$125 million	2015	Kickbacks
Millennium Health	$256 million	2015	Kickbacks
Genzyme	$33 million	2015	Off-label Promotion

Types of reimbursement disputes

Payers are continuing to discover new ways to pursue reimbursement recoveries from the life sciences industry. Increasingly, the cases in the pipeline are now related to kickback related matters with a focus on not only the contractual arrangements, but also considering the reasons and rationale behind the arrangement. Focus areas for disputes include:

Pricing

Life Science organizations face continued risk related to a multitude of pricing issues including price reporting to CMS, VA, and states including Texas, failing to follow the price reduction clause under Federal Supply Schedule (FSS) contracts, as well as pharmacy reimbursement matters related to Usual and Customary vs. acquisition cost. Medical device manufacturers face similar FSS issues, and proposed transparency legislation may extend their pricing risks substantially.

Marketing Issues

Payers allege off-label marketing, illegal kickbacks, Foreign Corrupt Practices Act (FCPA) violations, and other issues. These activities can be difficult to control and prevent or to identify and quantify after the fact. State and federal legislation that requires tracking, limiting, and reporting certain marketing expenses is expanding rapidly and serves both a significant compliance risk in itself as well as a potential plaintiff's roadmap for additional off-label marketing and kickback allegations.

Good Clinical, Laboratory, and Manufacturing Practices (GxP)

The DOJ has brought numerous cases alleging violations of the FCA resulting from violations of GxP, with a focus on links to patient harm. GxP-based FCA cases have the potential for staggering levels of damages which could dwarf even the largest of the recent promotional settlements. Despite the favorable outcomes in recent cases that limit the linkage between FCA and Food, Drug, and Cosmetic Act (FDCA) relators are expected to continue testing new strategies in pursuit of damages due to the potential profits to be made.[7,8]

KPMG services

When faced with government or commercial payer disputes, it is important to get KPMG involved early in order to minimize rework and maximize use of our perspectives on case strategy, early case discovery matters, as well as the cost containment that results from early quantification of potential liability and scaling the assistance for each unique situation. Payer dispute-related services offered by KPMG include:

Case Strategy Perspective
While case strategy is clearly the purview of counsel, our involvement with current and historical industry issues helps to bring an experienced alternative perspective that may enhance efficiency and outcomes.

Transactional Data Production
On the offensive side, we help counsel understand data availability, limitations, and uses in order to obtain the data necessary to support its legal arguments and favored damage theories. On the defensive side, we help legal counsel and the IT function to communicate effectively, be appropriately responsive, validate data pulls, and control data productions to prevent inconsistencies and errors.

Data Recovery & Management
We provide digital evidence collection, recovery, and analysis services. We host data and offer the Discovery Radar™ System; a customizable Web-based repository and review tool that allows counsel to conduct, manage, and monitor the entire discovery process.

Damage Calculations
We use the available cost, pricing, sales, and claims data to compute damage calculations and identify alternative settlement scenarios as negotiations progress.

General Case Support
We assist as needed with fact-finding, document assessments, data analytics, financial analyses, economic support, and other matters. When relevant, we can bring in other specialized skills and global capabilities through our network of member firms.

Expert Witness Service
We offer impartial and skilled assessment through expert reports, depositions, and trial testimony.

Alternative Dispute Resolution
We act as an objective arbitrator to resolve disputes or as mediator to help facilitate a negotiated settlement.

Settlement Compliance
We can help to establish Corporate Integrity Agreements (CIA) provisions that are clear, actionable, and reasonable. We have served as the Independent Review Organization (IRO), and we can make meaningful recommendations for control enhancements. We have also assisted monitors in executing their responsibilities under Deferred Prosecution Agreements (DPAs).

Dispute Avoidance
The best answer for any company is to avoid the litigation in the first place, and KPMG provides a broad range of proactive compliance strategies some of which are general in nature and others that are directly responsive to the types of payer disputes matters described above.

Why select KPMG?

KPMG has extensive reimbursement disputes and life sciences compliance experience and the knowledge and focus to support your needs. Select KPMG for reasons including:

Industry Experience
KPMG has significant experience with the life science industry, including the complex web of regulations, contracts, and data that unite the disparate players into a single industry.

Transactional Database Skills
We have experience in integrating disparate data sets to yield meaningful industry and situational insight through designing, building, and maintaining transactional databases from manufacturer, commercial payer and government payer sources.

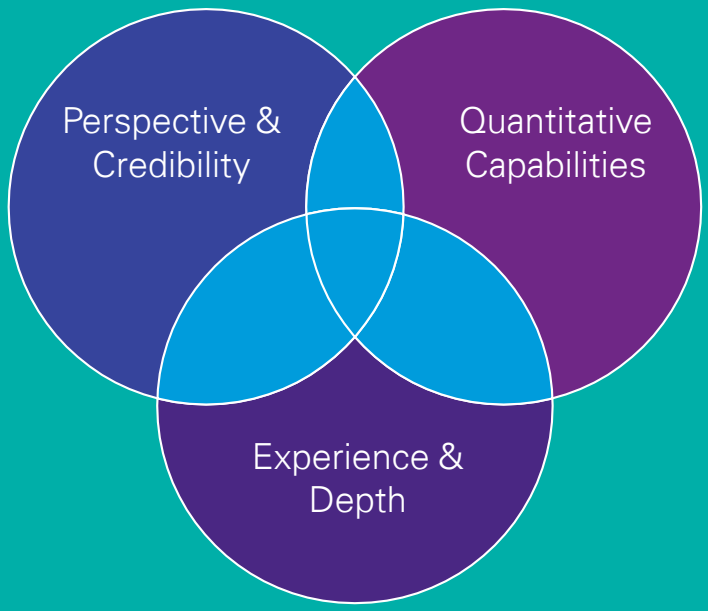
Analytical Capabilities
Our multifaceted professionals combine industry savvy and technical know-how to help increase efficiency and enhance insights. We help counsel narrow the scope of relevant claims, appropriately adjust amounts paid, and develop and pursue differing damage theories.

Credibility and Range
We are a "Big 4" accounting firm and bring expected objectivity, reliability, confidentiality, and credibility to every engagement along with the breadth of capabilities and experience of a national practice with global reach through our network of member firms.

Did you know?

- KPMG is ranked #1 in the 2015 National Law Journal's "Best of Chicago" Reader Rankings for six different life science litigation service areas.[9]
- KPMG is ranked #1 in the 2015 "Best of Legal Times " for five separate life science litigation service areas.[10]

- Objective external team
- Big 4 credibility
- Extensive active client base and work with top life science defense attorneys
- Thought leaders at conferences and in publications



- Capability to deal with datasets of all sizes
- Ability to analyze aggregate issues vs. sampling
- Business and data analytical people are the same
- Statisticians to perform statistical analyses

- Experience and knowledge extends from top to bottom
- Extensive client base
- Related work with underlying business operations

[1] http://www.policymed.com/2015/03/doj-hones-in-on-small-pharma-expects-companies-to-mine-their-own-data-for-misconduct-finds-speaker-p.html

[2] Yates, S.Q. (2015). Individual Accountability for Corporate Wrongdoing. Washington, D.C.: U.S. Department of Justice. Retrieved from http://www.justice.gov/dag/file/769036/download

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[4] King & Spalding, Pharmaceutical University, "Back to the Future for Pharma Prosecutions: From Off-Label to Kickbacks in the Evolving World of the FDCA & FCPA" November 10, 2015.

[5] Yates, S.Q. (2015). Individual Accountability for Corporate Wrongdoing. Washington, D.C.: U.S. Department of Justice. Retrieved from http://www.justice.gov/dag/file/769036/download

[6] King & Spalding, Pharmaceutical University, "Back to the Future for Pharma Prosecutions: From Off-Label to Kickbacks in the Evolving World of the FDCA & FCPA" November 10, 2015.

[7] http://www.justice.gov/opa/pr/2013/May/13-civ-542.html

[8] http://www.arnoldporter.com/resources/documents/Bloomberg%20 BNA_Recent%20 Appellate%20Decisions%20Suggest%20Significant%20 Limits%20on%20the%20 Use%20Of%20the%20False%20Claims%20 Act%20to%20Police%20Alleged%20 Violations%20of%20FDA%20 Regulations_03.28.2014.pdf

[9] http://pdfserver.amlaw.com/nlj/flipbook/BCHI2015/BestOfChicago_2015.pdf

[10] http://pdfserver.amlaw.com/nlj/flipbook/BLT2015/BLT2015.html#p=1

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