The Seventh Annual
Pharmaceutical Regulatory and Compliance Congress
and Best Practices Forum

# ADVANCED TACTICS FOR NEGOTIATION WITH THE GOVERNMENT AND PREPARING FOR A CIA

## NOVEMBER 8, 2006
## PRE-CONFERENCE SYMPOSIA
## PRE-CONFERENCE III

## CASE STUDY


**Facilitators:**

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# AGENDA

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| **8:30am – 9:15am** | **Attendee Introduction (All)OIG Negotiations Introduction (LSS)** |
| **9:15am – 9:30am** | **Objectives and Format of Session Introduction to Case Study Fact Pattern (LSS - Moderator)** |
| **9:30am – 10:30am** | **Case Study Team Break Out Groups "A-B-C" Facilitators (EBG and Industry Representatives )** |
| **10:30am -10:45am** | **Break (if needed)** |
| **10:45am - 11:30am** | **Presentations of Team Reports from the Case Study** |
| **11:30am – 12:00pm** | **Lessons Learned (Facilitators)** |

## CASE STUDY

It finally happened. For the last four years, Company X has been producing documents, conducting an internal investigation, meeting with Department of Justice ("DoJ") attorneys, preparing white papers and power points, and haggling over the settlement amount and damages methodologies. Now, DoJ and Company X have finally reached an oral tentative agreement to settle the federal government investigation as a civil healthcare fraud settlement for approximately $50 million to the government and an additional $200,000 in relator's counsel's legal fees.

Reaching this point required tremendous time and effort to receive internal corporate approval. Everyone at the senior levels of Company X now understands the litigation risks and sees the settlement as the right thing to do. Convincing senior management was not easy, though. Company X , a global pharmaceutical research and manufacturing company, based in New Zealand, with a U.S subsidiary. Senior management in the U.S. found it difficult to convince the foreign corporate parent of the value of settling the matter particularly given differences in the cultural understanding of the words "fraud" and "compliance." Having the U.S. subsidiary be a publicly traded company also made everything about the negotiations that much more intense.

It all began four years ago when Company X received a subpoena from the United States Attorney's Office in the District where Company's X's U.S. subsidiary home office is located. The subpoena, specifically, an Authorized Investigative Demand. had asked for a significant amount of documents related to financial relationships between Company X with all types of managed care entities. The subpoena also asked for documents related to government filings as to Medicaid Best Price. Indeed, over time, there were several subpoenas and witness interviews of both current and former employees until Company X was finally able to determine what was driving the government's investigation and what the government's allegations were regarding its relationship with managed care entities generally, and with HMO A, in particular.

It appeared that Mary Smith, a Company X account manager had suggested to HMO A that it request an unrestricted educational grant from Company X. Mary Smith suggested this activity to HMO A in her efforts to help better position Brand X, one of the branded drugs from Company X's product lines, onto HMO A's formulary. HMO A requested a grant in the amount of $50,000. Company X ultimately approved the grant request. Favorable formulary placement of Brand X followed.

A year after approving the grant request, Company X terminated Mary due to a reduction in force by Company X. After her termination, Mary filed a federal false claims act lawsuit in which she alleged misconduct at the direction of management. Interestingly, in addition to claiming that the grant was provided as an inducement for favorable formulary placement of Brand X on HMO A's preferred formulary, Mary also claimed that the grant really constituted an undisclosed discount for purposes of Medicaid Best

Price because the HMO never really needed the grant or ever actually use the grant for the purposes described in HMO A's grant request.

According to Mary, Brand X is a blockbuster drug for Company X. As a result, because of the high utilization of this product, if the government applied the grant as an undisclosed discount on the Medicaid Best Price the government has argued that the relevant damages could be $25 million. The government was willing to settle for twice that amount and no less than that. Having reached agreement on the appropriate releases and the settlement amount, the DoJ attorney has now asked your outside defense counsel to contact, Sue Sunshine, an OIG attorney, so that Company X can now reach a "settlement" with the DHHS OIG.

The DoJ attorney informed your outside counsel that Sue Sunshine has been involved with the case throughout the time period but has not been able to attend any of the meetings. The OIG has already stated that its exclusion authority is relevant and that the financial settlement alone is not enough for the OIG. The OIG is looking to impose ongoing integrity obligations through a Corporate Integrity Agreement ("CIA") in exchange for a waiver of OIG's permissive exclusion authority. Otherwise, OIG has said that it will proceed with an exclusion action!

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You are the people assigned to handle the CIA negotiations. The topics have been divided into three distinct teams. Please see below for a description of the three teams and the topics for each of these teams. Also, set forth below is:

- Additional information on Company X's compliance program
- Additional information regarding other investigations and relationships that might be relevant as you discuss the specific topics in your teams.
- List of additional resources for your use in the case study.

**Team A (Facilitators: Wendy Goldstein and Industry Representative)**

You have to prepare the materials and agenda for the first OIG meeting with Sue Sunshine.

- What is the **GAP ANALYSIS** that has to be done in order to prepare for this meeting?
- What should the agenda for the meeting be?
- What should be presented?
- What positions should Company X take with regard to potential integrity obligations?

**Team B (Facilitators: John Rah and Industry Representative)**

You have to prepare the inside counsel and senior management – including the parent company in New Zealand – about the **OIG AGREEMENT** that is likely to come out of these OIG negotiations.

- Is it a CIA or something else?
- What provisions of the CIA require modifications and what provisions are likely not to be subject to negotiation with the OIG?
- Knowing that the CIA is a very public document, how does that affect what you may want in the CIA?

**Team C (Facilitators: Lynn Shapiro Snyder and Industry Representative)**

You have to prepare the internal staff for life after settlement and, in particular, after the CIA becomes effective.

- What should be included in the **IMPLEMENTATION WORK PLAN**?
- What are you going to address for years one and after?
- How do you determine who has ownership of what obligations?
- What about internal and external communications?
- How does the Implementation Work Plan intersect with the work already being done by Teams A and B? Can Company X "walk and chew gum" at the same time?
- What resources are you going to need to help the Company comply with its CIA obligations?

Well, real life is not usually that simple!

1. Did you know that Company X also manufactures medical devices? Company X has a small DoJ investigation about a medical device for payments to prescribers about a "training" program that took place in Hawaii some time ago. There is no relator involved in that matter but the Assistant U.S. Attorney handling this matter is on the fence as to whether to consider this criminal misbehavior or pass it along for civil monetary penalties. It has been dormant for at least one year.

2. Company X has a co-promotion agreement with Company Y about a different drug product. Company Y has been under investigation for one year, and it appears that the investigation may involve the off-label promotion of the co-promoted product. Company X has never been touched by the government on this one – at least not yet.

3. Company X did have some issues with a different product years ago as to improper promotional activities and has been operating under an Assurance of Voluntary Compliance with several state Attorneys General. The topic there also was off-label promotional activities.

4. As to the current status of Company X's Global and U.S. based corporate compliance program, consider the following facts:

    a. There is a Global Department of Corporate Security that does surprise visits and financial audits of company operations. This Global Department also has issued a Global Code of Conduct.

b. The Chief Compliance Officer in the U.S. also is the General Counsel who reports to a Global General Counsel and not to the Global Security Officer.

c. The Chief Compliance Officer delegates compliance responsibilities on an as needed basis to "deputized" employees who may be from law, HR or elsewhere depending upon the need. There are only a few corporate compliance FTEs actually assigned to the CCO . Therefore, there is no Corporate Compliance Committee.

d. There is a U.S. Code of Conduct that mentions the company's Hot Line. This is maintained internally and not through an outside vendor. The records are kept by the CCO's executive assistant.

e. Recently, Company X instituted a policy for HR to conduct the screenings for new employees as to exclusion and debarment of employees. HR implemented that new policy about two months ago. HR is now developing a similar policy for vendors.

f.. Company X's Internal Audit Department conducts audits for SOX and SEC reporting purposes only

**RESOURCES AVAILABLE TO YOU INCLUDE THE FOLLOWING:**

1. **Table of Contents of a Corporate Integrity Agreement**
2. **A Draft power point that includes slides showing the seven elements of an effective corporate compliance program**
3. **The OIG Pharma Guidance**
4. **Samples of Actual Corporate Integrity Agreements; a Sample of an Actual Corporate Compliance Agreement; and a Sample of an Assurance of Voluntary Compliance Agreement**