



O'MELVENY & MYERS LLP

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## FCPA and International Anti-Corruption for the Pharmaceutical and Medical Device Industries



### Identifying and Correcting Books and Records Violations

*This presentation does not constitute legal advice. If you have questions regarding any transaction, please consult with inside counsel, who may confer with outside counsel depending on the facts.*

1. The Books and Records Provisions: An Overview

2. What are Books or Records?

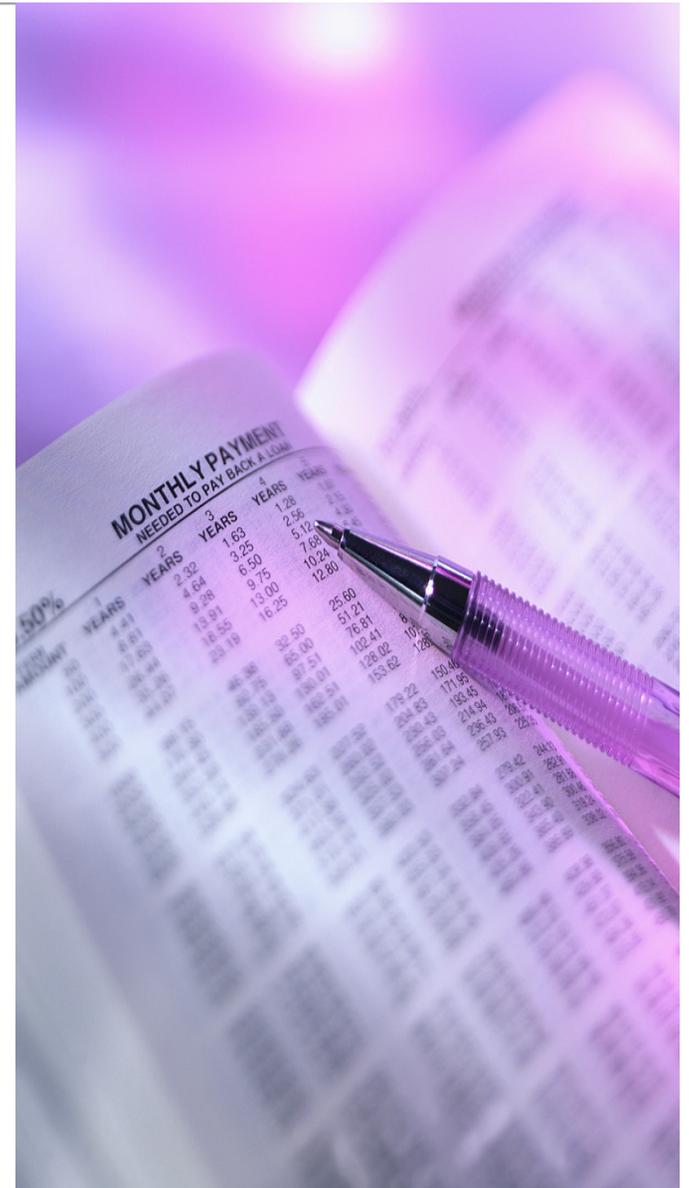
3. Responsibility for Subsidiaries' Books and Records

4. Recent Cases

5. Pharmaceutical and Device Cases Involving the Accounting Provisions

6. Key Issues

7. Correcting an Inaccurate Entry



# 1. The FCPA's Books and Records/Internal Controls Provisions: An Overview

Issuers must:

- Make and keep books and records in reasonable detail, to “accurately and fairly reflect the transactions and dispositions of the assets of the issuer.”
- Must devise and maintain a system of internal accounting controls to provide reasonable assurances that the company has accurate books and records and GAAP compliant financial statements.
- Enforced by DOJ and SEC against both companies and their officers and employees.

## a) Record-Keeping Provisions

### Securities Exchange Act of 1934, Section 13(b)(2)(A)

- Issuers shall “make and keep books, records, and accounts, which in **reasonable detail**, accurately and fairly reflect the transactions and dispositions of the issuer.”

### Securities Exchange Act of 1934, Section 13(b)(7)

- “**Reasonable detail**” means “such level of detail and degree of assurance as would satisfy prudent officials in the conduct of their own affairs.”

## a) Record-Keeping Provisions (cont'd)

Securities Exchange Act of 1934, Section 13(b)(5):

- “No person shall knowingly circumvent or knowingly fail to implement a system of internal accounting controls or knowingly falsify any book, record, or account described in [Section 13(b)(2)].”

Securities Exchange Act of 1934, Rule 13b2-1:

- “No person shall, directly or indirectly, falsify or cause to be falsified, any book, record or account subject to Section 13(b)(2)(A) of the Securities Exchange Act.”

## b) Internal Controls Provisions

### Securities Exchange Act of 1934, Section 13(b)(2)(B)

- The Exchange Act does not dictate a specific system of internal controls. Rather, the internal accounting controls should provide reasonable assurances that:
  - transactions are executed in accordance with management's authorization;
  - all transactions are recorded to permit GAAP accounting;
  - assets can only be accessed with management's authorization; and
  - recorded asset values are compared at reasonable intervals to existing assets and appropriate adjustments are made.

## c) Criminal and Civil Liability for Individuals

### Criminal Violations

Section 13(b)(4): No criminal liability except for violations for Section 13(b)(5)

- First time internal controls provisions used against a corporation:
  - *U.S. v. Siemens*, (2008)

### Civil Liability

Securities Exchange Act, Section 20(e) – Aiding and Abetting

- Federal Court: Any person that knowingly provides substantial assistance to another person in violation of the [books and records/internal controls provisions] shall be deemed to be in violation of such provision to the same extent as the person to whom such assistance is provided.

Securities Exchange Act, Section 21C

- Administrative Proceeding/Cease and Desist Order:
  - Commission may enter order against a person who is the “cause” of a violation of the Exchange Act “due to an act or omission the person knew or should have known would contribute to” the violation.

## d) Penalties

### Criminal Liability -- DOJ

- Maximum fine of \$25 million for organizations.
- Maximum fine of \$5 million and/or up to twenty years imprisonment for individuals.

### Civil Liability -- SEC

- Injunctive relief, cease and desist orders, penalties, and disgorgement. Exchange Act Section 21(d)(3).
- No scienter requirement for issuer liability.
- One circuit opinion suggests that no scienter required for individuals for violations of SEC Rule 13b2-1.
  - McConville v. SEC, 465 F.3d 780 (7<sup>th</sup> Cir. 2006)
- Issue: What is appropriate disgorgement for a books and records violation?

## 2. What are “Books or Records?”

### Unsettled Question

“[R]ecords which are not relevant to accomplishing the objectives specified in the statute for the system of internal controls are not within the purview of the recordkeeping provision.”

- Former SEC Chairman Harold M. Williams, 1981

“The purpose of the Books and Records statute was not merely to ensure accurate SEC public filings, but to reassure investors that, at the least, all books and records reflecting the economic events and activities of the corporation were accurate and honest.”

- *United States v. Jensen*, No. C 06-00556-2, 2008 U.S. Dist. LEXIS 7649, at \*27-30 (N.D. Cal. Jan. 25, 2008).

Accordingly, Board minutes are “books and records”

- Likely also includes ledgers, journal entries and documents relating to corporate transactions with third parties.

### 3. Responsibility for Subsidiaries' Books and Records

Securities Exchange Act of 1934, Section 13(b)(6)

Controlled Subsidiaries:

- Greater than fifty percent share ownership
- Government takes view that Issuer is strictly responsible for the subsidiary's compliance with internal controls and books and records requirements.

Non-Controlled Subsidiaries:

- Fifty percent share or less
- Issuer must proceed in good faith to use its influence to the extent reasonable to cause the subsidiary to maintain sufficient controls.

Issue:

- Effectively creates world-wide jurisdiction for books and records provisions.

# Responsibility for Subsidiaries: Enforcement Actions

## ITT Corporation, (Feb. 11, 2009)

- Settled injunctive action filed by SEC alleging payments to Chinese government officials by ITT's wholly-owned Chinese subsidiary, Naning Goulds Pumps LLC
- Payments totaled \$200,000 and generated profits of approximately \$1.1m
- Payments to government officials recorded as commission payments
- No U.S. contacts
- \$250,000 civil penalty plus disgorgement of \$1.4m

## Responsibility for Subsidiaries: Enforcement Actions (cont'd)

*Westinghouse Air Brake Technologies Corp.,*  
(Feb. 14, 2008)

- Enforcement action alleging that Westinghouse's fourth-tier Indian subsidiary made over \$137,400 in improper payments to Indian officials in order to have its competitive bids granted, or considered.
- "In order to generate the necessary cash, [the subsidiary] asked certain marketing agents to invoice it for services rendered.... In fact, the invoices were fictitious. No one rendered any services; the sole purpose of the invoices was to generate cash to make the unlawful payments."

## Responsibility for Subsidiaries: Enforcement Actions (cont'd)

- Subsidiary recorded marketing agents' invoices as "consulting expenses" and supplies, but subsidiary did not receive any services or supplies.
- No U.S. contacts
- Parent company charged by SEC with violations of accounting provisions and anti-bribery provisions.
- \$300,000 criminal fine and Non-Prosecution Agreement with DOJ
- \$87,000 civil penalty and disgorgement of \$288,251

## Responsibility for Subsidiaries: Enforcement Actions (cont'd)

### *The Dow Chemical Company*, (Feb. 13, 2007)

- Settled SEC cease and desist order alleging that a fifth-tier subsidiary of Dow had made numerous improper payments to Indian government officials to register several agro-chemical products in time for India's growing season.
- A contractor made payments on behalf of the subsidiary and "added fictitious charges called 'incidental charges' on its bills" to the subsidiary.
- "[F]rom 1996 to 2001, \$87,400 in payments were made to state inspectors and other state officials. None of these payments were properly recorded in [the subsidiary's] books."
- No knowledge by parent corporation that improper payments were made but parent corporation was charged.

## 4. Recent Cases

### SEC v. Baker Hughes Inc., (Apr. 26, 2007)

Baker Hughes agreed to pay over \$44 million in settlements with the DOJ and SEC. The government alleged that money was paid to agents to bribe government officials in Kazakhstan. The SEC also alleged violations of the books and records provisions regarding payments in five additional countries.

- payments to agent “inaccurately recorded” as “commissions,” “fees” and “legal services”
- payments to second agent “inappropriately recorded” as “commission”
- payment to agent described as “miscellaneous expenses”

## 4. Recent Cases (cont'd)

### Lucent Technologies Inc., (Dec. 21, 2007)

- Lucent settled with government by paying \$2.5 million. It was alleged that the company paid over \$10 million for approximately 1,000 Chinese officials to travel to the United States and elsewhere, where the officials spent little time in Lucent's facilities, in return for favorable treatment of Lucent's bids.
- “[T]he Chinese visitors proceeded to travel to the United States at Lucent's expense solely for sightseeing, entertainment and leisure purposes. Lucent improperly recorded its expenses for these visitors' sightseeing trip in its 'Factory Inspection' account, despite the fact there had been no visit to a Lucent factory at any point during the visit.”
- “The visit consisted of five days of Lucent training in Orlando, Florida, and, thereafter, sixteen days of sightseeing, entertainment and leisure.... The expenses for this trip were improperly recorded in Lucent's accounting records as 'Service Rendered – Other Services.’” This account was typically used to credit “other services” and was not intended to be for travel expenses.

## 4. Recent Cases (cont'd)

- “Emery Transnational did not characterize these payments in its books and records as bribes”
  - *In the Matter of Con-Way, Inc.*, (Aug. 27, 2008)
- Recording Oil-For-Food subsidy payments as a “special project discount.”
  - *SEC v. Flowserve Corp.*, (Feb. 21, 2008)
- Recording Oil-For-Food subsidy payments to Jordanian distributor as sales deductions” and “other commissions.”
  - *SEC v. Ingersoll-Rand Company*, (Oct. 30, 2007)
- Recording cash payments to tax officials as “taxes” and “payroll tax expenses.”
  - *Bristow Group Inc.*, (Sept. 26, 2007)

## 5. Pharmaceutical and Device Cases Involving the Accounting Provisions

Akzo Nobel N.V., (Dec. 20, 2007)

- Sale of pharmaceuticals in Iraq through agents and consultants under the UN Oil-for-Food Program.
- Books and records violation for increasing agents' commissions to allow agents to pay kickbacks to Iraqi regime while recording the payments as legitimate commissions.
- Internal controls violation due to "extent and duration" of the payments (there were four), the improper recording of them, and the failure of management to detect them.

## 5. Pharmaceutical and Device Cases Involving the Accounting Provisions

*Immucor, Inc. and Gioacchino De Chirico*, (Sept. 27, 2007)

- Payment through an agent to a hospital director of a consulting fee where no services were actually provided, in connection with sale of medical equipment to hospital in Italy. Charges brought against both company and President/COO.
- Books and records violation for failing to properly record the disbursement, falsely booking the entry as an expense for consulting services that did not occur, and filing the related false invoice among Immucor's books and records.
- Internal controls violation in light of this single transaction (the value of which was approximately \$16,000) and the false recording of it.

## 5. Pharmaceutical and Device Cases Involving the Accounting Provisions

### Schering-Plough Corporation, (June 8, 2004)

- Thirteen contributions to a bona fide charitable organization that restored historic sites in Poland and was founded by the director of a government health authority; contributions were made to influence the director with respect to the company's products.
- Books and records violation for structuring the payments so they were below relevant approval limits and providing false medical justifications, such as "support of health campaign," "financing second stage of research," "support of a coronary disease prevention program and promote the image of the company in the medical community," etc.
- Internal controls violation due to failure to conduct due diligence and failure to detect improper payments where foundation was largest recipient of promotional donations, foundation was the only recipient of multiple donations, and sales of two products increased disproportionately compared with sales of those products elsewhere in Poland.

## 5. Pharmaceutical and Device Cases Involving the Accounting Provisions

*Syncor International Corporation*, (Dec. 10, 2002)

- Provision of commissions, referral fees, gifts, furniture, sponsorships to attend seminars, medical supplies, funds to cover costs of temporary employees and other benefits to doctors and hospitals, which were both government and non-government, in Taiwan, Mexico, Belgium, Luxembourg, France, Germany, Italy, and Greece, in connection with sales of radiopharmaceutical products.
- Books and records violation for inaccurately recording such items as promotional and advertising expenses or capital or business expenses, as well as recording some such expenses in various business accounts, including accounts of the wrong subsidiary, in order to avoid detection.
- Internal controls violation in light of above-described control failures.

## 5. Pharmaceutical and Device Cases Involving the Accounting Provisions

Siemens Aktiengesellschaft, (Dec. 12, 2008)

- Payments by medical solutions operating group to “consultants” and other intermediaries, as well as pooling funds in “internal commission accounts” on the balance sheet for purposes of such payments, in connection with the operating group’s sales of medical products and equipment and health care information services worldwide, particularly in Vietnam, China and Russia.
- Books and records violation for mischaracterizing such payments as legitimate payments to consultants and other third parties.
- Internal controls violation in light of the improper use of consultants, improperly described balance sheet accounts, and numerous other failures throughout Siemens’ other worldwide operations.

## 5. Pharmaceutical and Device Cases Involving the Accounting Provisions

### Diagnostic Products Corporation, (May 20, 2005)

- Commissions paid by Chinese subsidiary to procurement employees of government hospitals in China in connection with sales of medical equipment.
- Books and records violation for mischaracterizing such payments as legitimate sales expenses.
- Internal controls violation in light of above-described conduct.

## 6. Key Issues

- No scienter required for civil liability
- No materiality
- No connection to United States required for civil liability
- Applies to inaccurately recorded payments to privately-owned companies

## 7. Correcting an Inaccurate Entry

### No Clear Regulatory Guidance

- Requirement for Issuers is to “make and keep” accurate books and records
- Making changes to books and records ensures:
  1. Accuracy, and
  2. Transparency

# QUESTIONS



## **RICHARD W. GRIME**

O'MELVENY & MYERS LLP  
1625 EYE STREET NW  
WASHINGTON, DC 20006  
(202) 383-5178  
RGRIME@OMM.COM

## **JAY HOLTMEIER**

WILMERHALE  
399 Park Avenue  
New York, New York 10022  
(212) 295-6413  
JAY.HOLTMEIER@WILMERHALE.COM