

United States Department of Justice Foreign Corrupt Practices Act Initiative for Pharmaceutical and Medical Device Manufacturers



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Kirk Ogrosky
Deputy Chief
Steven Kim
Trial Attorney
Fraud Section, Criminal Division
U.S. Department of Justice

Origins



FCPA Enacted in 1977 - Legislative History: “More than 400 corporations have admitted making questionable or illegal payments. The companies, most of them voluntarily, have reported paying out well in excess of \$300 million in corporate funds to foreign government officials, politicians, and political parties. These corporations have included some of the largest and most widely held public companies in the United States; over 117 of them rank in the top Fortune 500 industries Sectors of industry typically involved are: drugs and health care; oil and gas production and services; food products; aerospace, airlines and air services; and chemicals.

-- *Excerpted from House Report No. 95-640*

The Foreign Corrupt Practices Act

15 U.S.C. §§ 78m, 78dd-1, *et seq.*

ACCOUNTING PROVISIONS:

- Books and Records: make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer; and
- Internal Controls: devise and maintain a system of internal accounting controls

ANTIBRIBERY PROVISIONS:

- Prohibit payment, offer of payment, or authorization of payment of bribes, directly or indirectly, to foreign officials, foreign parties, foreign party officials, and foreign candidates for public office

Antibribery Provisions: Elements of the Offense

15 U.S.C. §§ 78dd-1, 78dd-2, 78dd-3

- “Willfully”
- Corrupt intent (includes deliberate ignorance)
- Offer, payment, promise to pay, or authorization of the payment of any money or anything of value
- Officials of foreign governments, their instrumentalities, and public international organizations; political parties; party officials; candidates for office; or intermediaries
- *Quid pro quo*
- Assist in obtaining or retaining business (“business nexus”)

Jurisdiction

- Issuers (§ 78dd-1) and Domestic Concerns (§ 78dd-2)
 - in the U.S.: use of the U.S. mails or any means or instrumentality of interstate commerce
 - outside the U.S.: nationality sufficient (“*nationality jurisdiction*”)
- Foreign “Persons” (§ 78dd-3)
 - an act “while in the territory of the United States” (“*territorial jurisdiction*”)
 - coverage of agents of issuers and domestic concerns may be wider

Definitions

- “Issuers”
 - Registered securities under Title 15 (*i.e.*, traded on U.S. exchanges)
 - American Depositary Receipts (ADRs) (indirect trading on U.S. exchanges)
- “Domestic Concerns”
 - Citizen, national, or resident of U.S.
 - Corporation, partnership, unincorporated organization, etc., with PPB in U.S. or organized under laws of a State of U.S.
- Any “Person” other than an issuer
- Officers, directors, employees, stockholders and agents of the above

“Money or Anything of Value”

- Offer; payment; promise to pay; or authorization of payment
- In addition to money or cash equivalent:
 - “Anything of value” includes trips; golf outings; charitable contributions; college scholarships
 - Domestic bribery: cars, etc.
 - Subjective analysis – from perspective of recipient

Recipients

- Foreign official
 - of a foreign government or of a public international organization
- Foreign political party
- Foreign political party official
- Candidate for foreign political office
- Any person (i.e., intermediary) – requires knowledge or willful blindness to fact that third person is a conduit to one of the above

Who is a “Foreign Official”?

- The obvious: heads of state; parliamentarians; ministers; employees of government agencies; members of the military.
- State-owned enterprises (an “agency or instrumentality”) – degree of control, rather than formal ownership, is the key
 - “golden share”
 - right to appoint officers
 - board control
 - *E.g.*, doctors and lab personnel at government-owned hospitals (Syncor) and general director of state-owned enterprise

Public Foreign Health Systems

- Many foreign healthcare systems owned or controlled by the government
- Most foreign healthcare providers who work at government-run or government-controlled hospitals, clinics, or laboratories qualify as “foreign officials”
- Global healthcare companies particularly vulnerable given increasing internationalization of industry and expectation of quid pro quo in certain countries

Corrupt Purpose

- Payment or gift must be for the purpose of
 - Influencing act of such person in his official capacity;
 - Inducing such person to do or omit to any act in violation of his lawful duty; or
 - Inducing such person to use his influence with a foreign government or instrumentality thereof to affect or influence any or act of decision
 - Securing any improper advantage

Quid pro quo: The bribe must be in consideration for the foreign official's anticipated conduct.

Mens Rea

- A company or individual has the requisite knowledge if:
 - such person is aware that such person is engaging in such conduct, that such circumstances exists, or that such result is substantially certain to occur, [or]
 - such person has a firm belief that such circumstances exists or that such result is substantially certain to occur.

United States v. Frederic Bourke, Jr., No. 05-CR-518 (S.D.N.Y.)

- Jury Charge: “when knowledge of the existence of a particular fact is an element of the offense, such knowledge may be established if a person is aware of a high probability of its existence and consciously and intentionally avoided confirming that fact. Knowledge may be proven in this manner if, but only if, the person suspects the fact, realized its high probability, but refrained from obtaining the final confirmation because he wanted to be able to deny knowledge.”

Business Nexus

- Payment must be to “assist in obtaining or retaining business for or with, or directing business to, any person”
- United States v. Kay, 359 F.3d 738 (5th Cir. 2004) — Case involved payment of bribes by executives of American Rice, Inc. to Haitian customs and tax officials to reduce or avoid duties and taxes. Court found that the “business nexus” requirement was not limited to obtaining business from the corrupt official’s government and instead turned on whether, by paying bribes, the defendants *intended* to assist the company in obtaining business from any person.

Facilitation Payments Exception

- Law excludes “facilitating or expediting payment[s] . . . the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official”
- “Routine governmental action” means only an action which is ordinarily and commonly performed by a foreign official in—
 - obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country;
 - processing governmental papers, such as visas and work orders;
 - providing police protection, mail pick-up and delivery, or scheduling inspections associated with contract performance or inspections related to transit of goods across country;
 - providing phone service, power and water supply, loading and unloading cargo, or protecting perishable products or commodities from deterioration; or
 - actions of a similar nature.
- Does **NOT** mean a decision to award new business to or to continue business or to assist in same.
- **These are typically routine, small currency, non-discretionary transactions.**

Defenses:

- Bona fide expenditures directly related to (a) the promotion, demonstration or explanation of products or services, or (b) the execution or performance of a contract
 - Factory or site visits (but not side trips)
 - Product samples (of nominal value in context)
 - Actual expenses (but not “walking around \$\$\$”)
- Payment or gift was lawful under written laws and regulations of foreign country
 - Purpose seems to be to codify prior enforcement policy, which permitted American companies to employ foreign officials for tasks unrelated to their public duties, where permitted by foreign law.
 - Extremely narrow in practice

Penalties

- Individuals:

- Imprisonment of up to 5 years; and fine of up to \$250,000;
- Alternative fine of up to twice the gross gain or loss caused by the corrupt payments

- Corporations:

- Fine of up to \$2 million or up to twice the gross gain or loss caused by the corrupt payments
- Alternative dispositions: Deferred or Non-Prosecution Agreements; Monitors; Compliance Programs

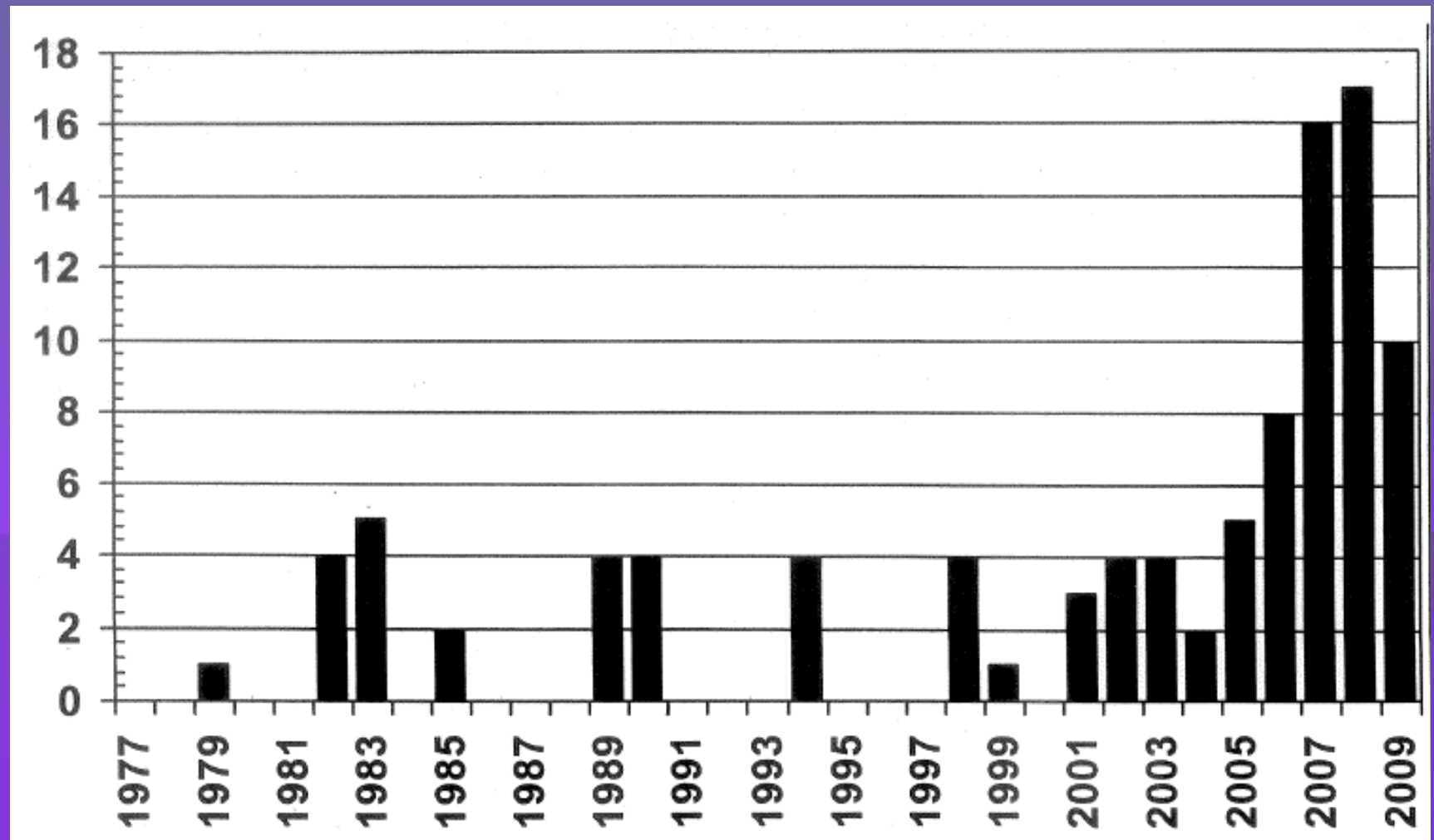
Collateral Consequences

- Possible exclusion from Medicare and Medicaid Programs
- Private shareholder litigation
- Foreign investigations
- Legal, accounting, and other costs associated with internal investigation and legal defense

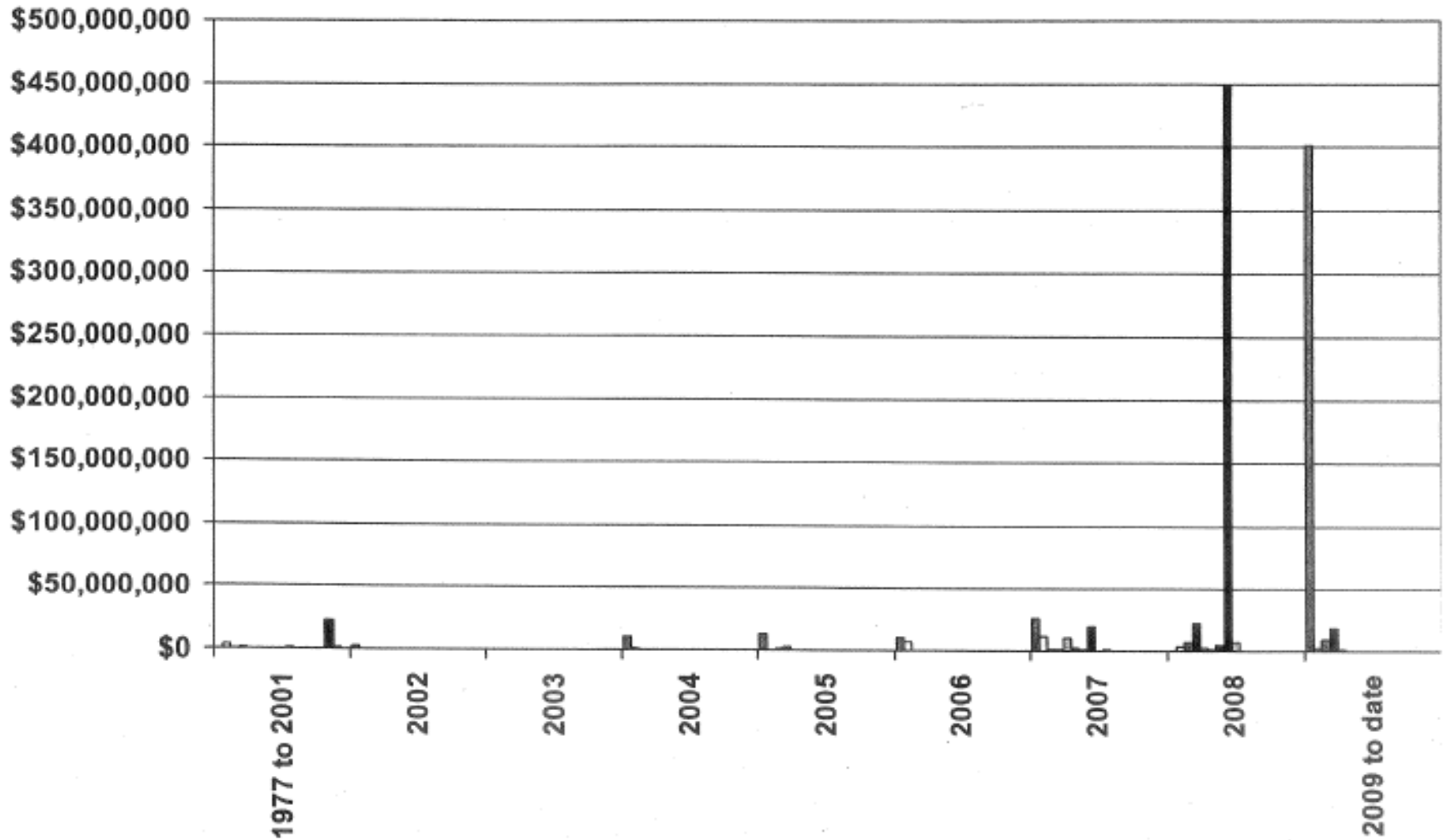
International Conventions

- **OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions**
 - Ratified by U.S. in December 1998
 - Implementing legislation effective November 10, 1998
- **Inter-American Convention on Corruption**
 - Ratified by U.S. in September 2000
- **Council of Europe: Criminal Law Convention & GRECO**
 - GRECO joined by U.S. in September 2000
 - Convention signed by U.S. in October 2000
- **United Nations Convention**
 - Ratified by U.S. in November 2006

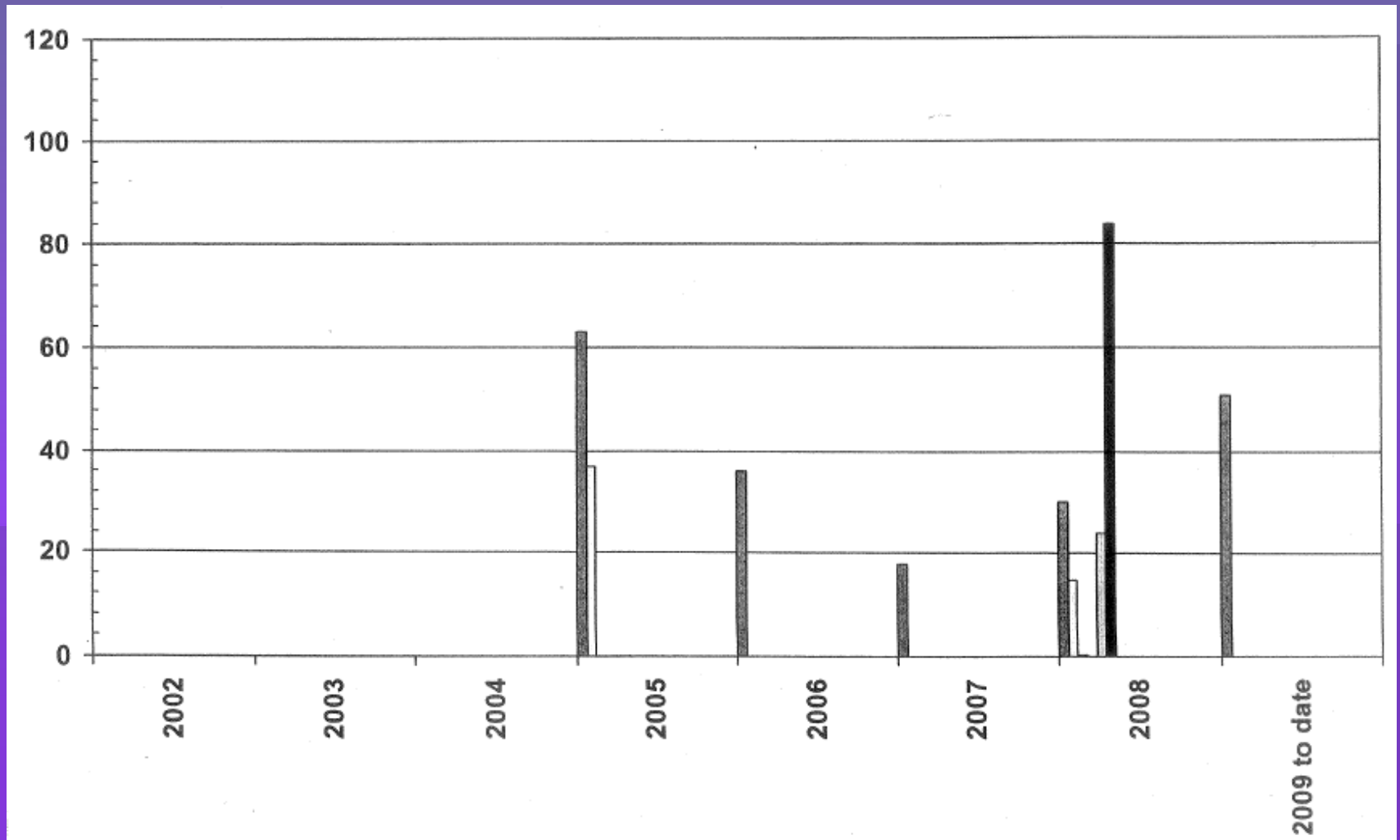
Number of DOJ Prosecutions: 1977-Present



FCPA Corporate Penalties



FCPA Individual Sentences



Example: Pharma Co.

- Pharma Co. – U.S. based pharmaceutical company and issuer
- Conduct takes place in several foreign countries where the government controls healthcare
- Consulting Agreements
 - Pharma Co. paid public physician to ensure that Pharma Co. products would be approved for reimbursement
 - Pharma Co. paid public physician of state-run hospital based on the quantity of Pharma Co. drugs that were purchased by that state-run hospital

Pharma Co.

- Hospital Donations
 - Pharma Co. donated medical equipment and supported overseas travel by state healthcare providers to attend medical conferences
 - Donations valued as a percentage of Pharma Co. products that were purchased by those state-run hospitals

Pharma Co.

- Cash payments to public healthcare providers in return for prescribing Pharma Co. drugs
 - Typically through collusion with third party vendors
- Gifts to public physicians in return for prescribing Pharma Co. drugs
 - E.g., televisions, cameras, watches, etc.

Pharma Co.

- Travel
 - Pharma Co. paid public physicians to attend medical conferences with little/no scientific purpose
- Lecture Fees/Honoraria
 - Pharma Co. paid public healthcare providers for lectures that were never given
- Charitable Donations
 - Pharma Co. made cash or in-kind donations on behalf public physicians to hospitals/universities with which they were associated
 - Foundations fictitious and/or controlled by those physicians

Pharma Co.

- Regulatory Approval/Licensing
 - Foreign country has multiple layers of regulatory approval before pharmaceutical products can be sold in that country
 - Pharma Co. paid foreign officials to ensure Pharma Co. products received all necessary approvals
 - Pharma Co. also paid foreign officials to expedite all necessary import licenses

Pharma Co.

■ Distributors

- Pharma Co. had to rely on foreign distributors to import and distribute their products in that country
- Pharma Co. entered into agreements with foreign distributors that were controlled by foreign officials
- Payments made to offshore accounts of third-party shell companies that were associated with those distributors/officials
- In return, Pharma Co.'s products were approved for reimbursement and distributed by those distributors

Pharma Co.

- In other instances, Pharma Co. made payments to a third-party company that were tied to commissions from Pharma Co. sales to the foreign distributor that was associated with that third-party company
 - Separate consulting agreement with third-party company
- Distributors also received price discounts on Pharma Co. products, in violation of the foreign country's regulations

Pharma Co.

- Intermediary Payors
 - Pharma Co. used third-party companies to make payments to public officials/public healthcare providers
 - Actual and virtual companies