

An Update on FCPA Enforcement by the Department of Justice in the Life Sciences Industry

Harvard Health Policy Review and Rx Compliance Report
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John S. (Jay) Darden
Partner | Patton Boggs LLP
2550 M Street, NW | Washington, DC 20037
202-457-6427 (office direct) | 202-725-7387 (cell)
jdarden@pattonboggs.com
Admitted only in Georgia
Supervised by Principals of the Firm

FCPA in a Nutshell



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FCPA Anti-Bribery Provisions

- Anti-bribery provisions apply to:
 - “Issuers” (15 U.S.C. § 78dd-1)
 - “Domestic concerns” (15 U.S.C. § 78dd-2)
 - Any “person” other than an “issuer” or “domestic concern” who “while in the territory of the U.S.” corruptly makes use of the mails or “any means or instrumentality of interstate commerce” (15 U.S.C. § 78dd-3)
- Anti-bribery provisions prohibit:
 - “any offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give or authorization of the giving of *anything of value*” (15 U.S.C. § 78dd-3(a))
 - Made to a “*foreign official*”
 - For the purpose of *obtaining or retaining business*
 - Requires “corrupt intent”

FCPA Books and Records Provisions

- Books and records provisions apply to “issuers”:
 - Registered securities (15 U.S.C. § 781)
 - Otherwise required to file reports (15 U.S.C. § 78o(d))
- Books and records provisions require issuers to:
 - 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 (15 U.S.C. § 78m(b)(2)(A))

FCPA Internal Controls Provisions

- Internal controls provisions apply to “issuers”:
 - Registered securities (15 U.S.C. § 78l)
 - Otherwise required to file reports (15 U.S.C. § 78o(d))
- Internal controls provisions require issuers to:
 - devise and maintain *a system of internal accounting controls* sufficient to provide reasonable assurances that –
 - (i) transactions are *executed in accordance with management's general or specific authorization*;
 - (ii) transactions are recorded as necessary (I) to permit *preparation of financial statements in conformity with generally accepted accounting principles* or any other criteria applicable to such statements, and (II) to *maintain accountability* for assets (15 U.S.C. § 78m(b)(2)(B))

Launch of the “Pharma Initiative”

Lanny Breuer, Assistant Attorney General, Criminal Division:

I would like to share with you this morning one area of criminal enforcement that will be a focus for the Criminal Division in the months and years ahead – and that’s the application of the Foreign Corrupt Practices Act (or “FCPA”) to the pharmaceutical industry.

According to PhRMA’s 2009 Membership survey, close to \$100 billion dollars, or roughly one-third, of total sales for PhRMA members were generated outside of the United States, where health systems are regulated, operated and financed by government entities to a significantly greater degree than in the United States. . . .

In the course of those interactions, the industry must resist short-cuts. It must resist the temptation and the invitation to pay off foreign officials for the sake of profit. It must act, in a word, lawfully.

November 12, 2009

FCPA Criminal Enforcement – Fraud Section, Criminal Division

No investigation or prosecution of cases involving alleged violations of the antibribery provisions of the . . . FCPA . . . or of related violations of the FCPA’s record keeping provisions . . . *shall be instituted without the express authorization of the Criminal Division.*

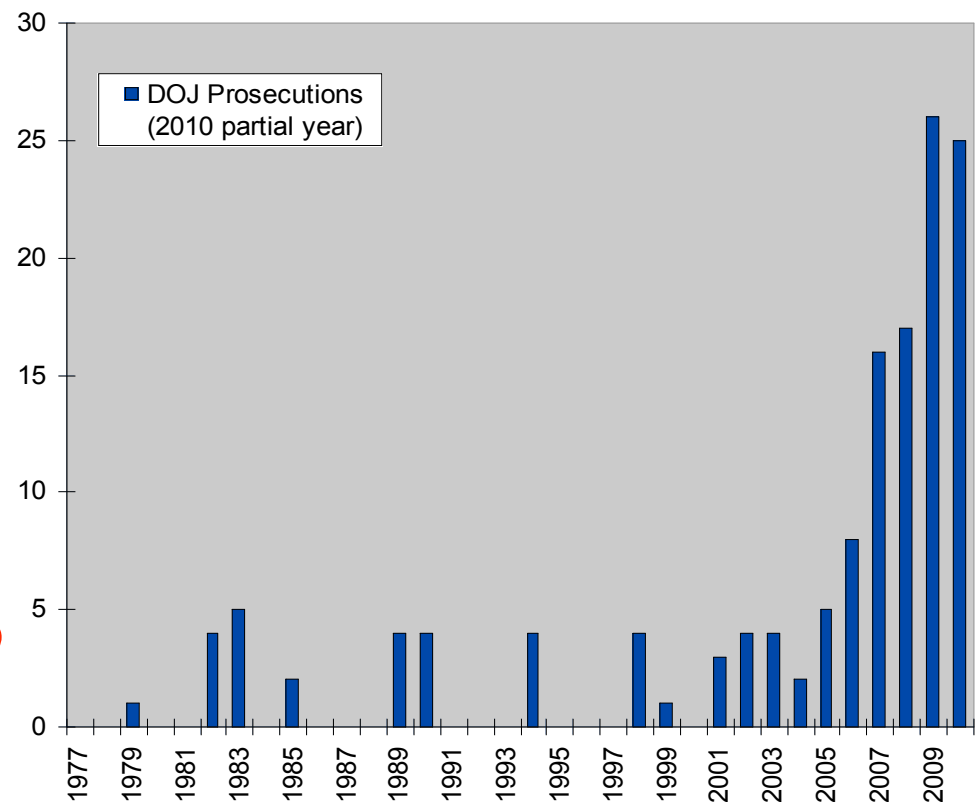
Unless otherwise agreed upon by the AAG, Criminal Division, *investigations and prosecutions of alleged violations of the antibribery provisions of the FCPA will be conducted by Trial Attorneys of the Fraud Section.* Prosecutions of alleged violations of the *record keeping provisions, when such violations are related to an antibribery violation,* will also be conducted by Fraud Section Trial Attorneys, unless otherwise directed by the AAG, Criminal Division.

USAM 9-47.110

2005 to Present: Significant Increase in DOJ Enforcement

Key Stats Since 2005:

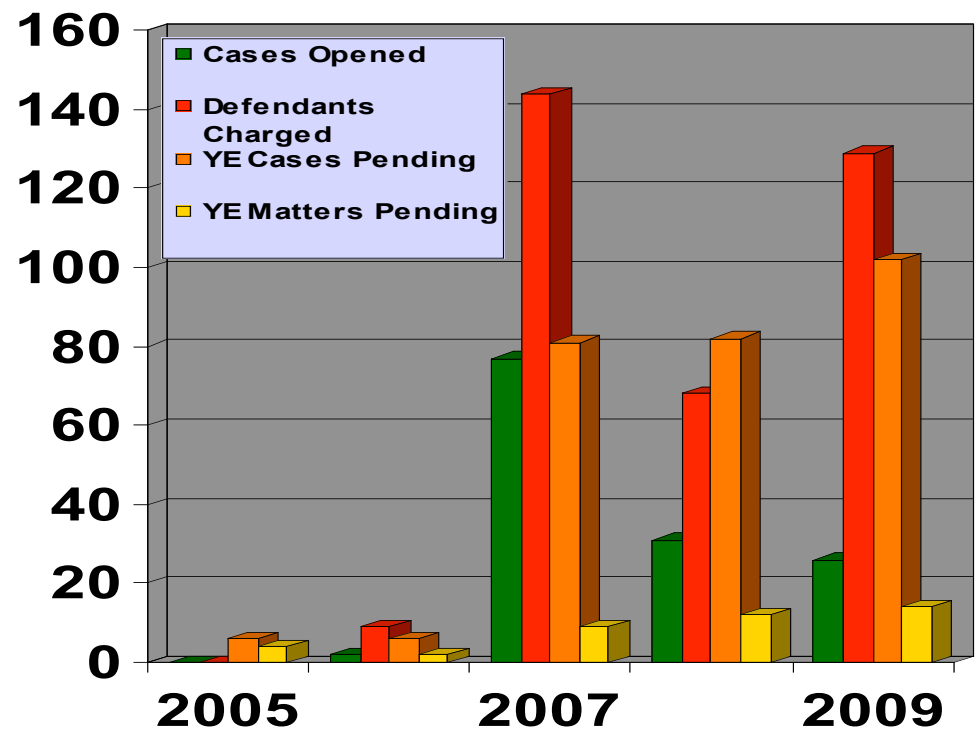
- 40+ corporate resolutions
- \$2+ billion in fines
 - 6 largest in last 22 months
- 75+ individuals charged
 - 47 since beginning of 2009



Criminal Fraud Section: Increase in Health Care Fraud and Abuse Enforcement

Key Stats Since 2007:

- 800+ individuals charged
- \$1.85+ billion in false claims
- Longer prison sentences
- Cooperation with USAOs



FCPA Criminal Enforcement – Fraud Section, Criminal Division Personnel Changes

Chief

Denis McInerney

FCPA

Deputy Chief (FCPA)

Chuck Duross

Assistant Chiefs

Bill Stuckwisch

Nat Edmonds

Health Care Fraud

Deputy Chief (HCF)

Hank Walther

Assistant Chief

John Neal

Areas of Risk

Country Risk

- Any country with state run health care system, state-owned hospitals
- Brazil, China, Croatia, Germany, Greece, Italy, Poland, Russia, Saudi Arabia, Slovakia, others

Partner Risk

- Joint ventures, third-party agents

“Foreign officials” Risk

- Any professional/employee of state health care system
- Physicians, nurses, hospital officials (CEOs, purchase agents, etc.), state formulary committees, government research officials

Payment Risk

- Use federal anti-kickback cases as a guide, e.g. direct payments, writing/speaking fees, preceptorships, conferences
- Tenders
- Distributors/third-parties

Internal “red flags”

- Payments to third countries
- Payments to third parties
- Payments above market rates for purported service
- Lack of documentation of services provided
- Overcharges
- Discounts
- Contract addenda, retro-active documents
- Tender process
- Travel/entertainment
- Marketing budget

Principles of Federal Prosecution of Business Organizations – Factors

1. Nature and seriousness of the offense
2. Pervasiveness of wrongdoing within organization
3. Organization's history of similar misconduct
4. Organization's timely and voluntary disclosure of wrongdoing (i.e., "cooperation")
5. Existence and effectiveness of organization's pre-existing compliance program
6. Organization's remedial actions
7. Collateral consequences arising from potential prosecution
8. Adequacy of prosecution of individuals responsible for organization's malfeasance
9. Adequacy of alternative remedies

USAM Section 9-28.300