

PHARMACEUTICAL
AND REGULATORY
COMPLIANCE
CONGRESS

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INSIGHTS INTO THE DEPARTMENT OF JUSTICE

- The views expressed are those of the author. They do not necessarily reflect the position of the Department of Justice and are not binding on the Department of Justice.

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United States Department of Justice

Civil Division

Office of Consumer Litigation

(202-307-3009)

- The Office of Consumer Litigation (OCL), a section in the Civil Division of the Department of Justice (DOJ), enforces through civil litigation and criminal prosecutions a number of Federal statutes that protect the public health and safety and protect consumers from unfair practices.
- 28 C.F.R. 0.45(j)
- What we do is on the Web.
- OCL monograph is at:
<http://www.usdoj.gov/civil/ocl/monograph/index.htm>

UNITED STATES ATTORNEYS OFFICES

- 93 Presidential Appointees
- Although the distribution of caseload varies between districts, each has every category of cases and handles a mixture of simple and complex litigation.
- Each United States Attorney exercises wide discretion in the use of his/her resources to further the priorities of the local jurisdictions and the needs of their communities.
- <http://www.usdoj.gov/usao/>

HHS and DOJ Health Care Fraud and Abuse Control Program Annual Report FY 2001

- <http://www.usdoj.gov/dag/pubdoc/hipaa01fe19.htm#a>
- The detection and elimination of health care fraud and abuse is a top priority of Federal law enforcement.
- Our efforts to combat fraud were consolidated and strengthened considerably by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

HIPAA

- HIPAA established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program).
- The Program falls under the joint direction of the Attorney General and the Secretary HHS, acting through the Inspector General.
- It is designed to coordinate Federal, state, and local law enforcement activities with respect to health care fraud and abuse.

HIPAA

In the Program's fifth year of operation, Federal and state enforcement and oversight agencies have continued their collaborative efforts to:

- 1) Identify and prosecute the most egregious instances of health care fraud
- 2) Prevent future fraud or abuse
- 3) Protect program beneficiaries

Criminal Division AAG Discusses White Collar Crime Priorities

Criminal Division Assistant Attorney General (AAG) Michael Chertoff emphasized the continuing importance of health care fraud enforcement at the American Bar Association's annual Health Care Fraud Institute on May 16, 2002. Noting that in the immediate aftermath of the terrorist attacks, white collar investigators directed their efforts toward counter-terrorism work, AAG Chertoff said that those investigators have returned to their assignments and the DOJ remains committed to white collar enforcement work.

VIEWS OF ROBERT MCCALLUM, ASSISTANT ATTORNEY GENERAL CIVIL DIVISION

- In a recent speech, McCallum pledged his support, as well as that of Attorney General Ashcroft and Deputy Attorney General Thompson, of the False Claims Act. All promised vigorous enforcement of the law.
- McCallum noted that the DOJ works hand in hand with
 - 1) The Centers for Medicare and Medicaid Services
 - 2) The HHS Office of General Counsel
 - 3) The staff at the HHS Office of the Inspector General

McCallum, continued. . .

On the topic of corporate compliance programs and self-disclosure. . .

- McCallum emphasized that the DOJ fully encourages and endorses the efforts of industry to promote compliance programs and self-governance, notably in the health care industry, as law enforcement efforts have been stepped up in that area.

McCallum, continued. . .

- McCallum stated that compliance programs must
 - 1) Be effective
 - 2) Have high-level executive support
 - 3) Address the root causes of fraud
 - 4) Provide adequate mechanisms to prevent and detect them before they result in harm to the procurement or health care systems

This should include a means by which industry can disclose wrongdoing that it does detect to the government.

McCallum, continued. . .

- McCallum credited HHS-OIG and the IG offices at other agencies for being instrumental in providing guidance geared toward assisting industry with developing comprehensive programs.
- McCallum: “*We applaud both the agencies and industry for their combined efforts.*”

History of Enforcement

- The DOJ has been pursuing fraud and misconduct in the pharmaceutical industry for at least 30 years. See *Food and Drug Law Journal*, 46, 781-793.
- OCL's priorities are enforcing laws against health care fraud and unsafe products and attacking fraud, including on the Internet.

Lawyer joke---how many lawyers does it take to set up a Web site?

How Do Cases Come to DOJ?

- Qui Tam Actions
- FDA Referrals
- Grand Jury Investigations-- Subpoena
- Interviews
- Search Warrants
- Administrative Warrants/Subpoenas
- HHS Referrals
- Informants
- Competitors
- Science
- Cooperating Witnesses

HHS IG GUIDELINES

- http://www.oig.hhs.gov/fraud/docs/compliance_guidance/draftcpgharm09272002.pdf

FDA Guidelines and Sentencing Guidelines

- U.S. v. Park, 421 U.S. 658 (1975), gives FDCA cases special consideration. (Defendant not where violations occurred. Government must show that defendant had, by reason of his position in the corporation, responsibility and authority either to prevent or to correct violations and failed to do so.)
- Good Manufacturing Procedures
- Sales Incentives
- 2 B1.1

Enforcement Options

Alternative Civil Remedies Under the Food, Drug, and Cosmetic Act

- Injunction
- Product seizure and condemnation
- Civil penalties
- Disgorgement-- United States v. Universal Management, 999 F. Supp. 974 (N.D. Ohio 1997), aff'd, 191 F.3d 750 (6th Cir. 1999).

HEALTH CARE FRAUD

False Claims Act

- United States v. University of Minnesota,
992 F. Supp. 1097 (D. Minn. 1998).

HEALTH CARE FRAUD

- Prosecutions and enforcement against pharmaceutical products-- United States v. Baldev Raj Bhutani, 175 , F.3d 572 (7th Cir. 1999), 266 Fed.3d 661 (7th Cir. 2001), cert denied U.S. (2002).
- Qui Tam actions will follow up on TAP, GMP standards.
- FDCA expertise will be valuable in False Claims Act cases.

HEALTH CARE FRAUD STATUTES

Conspiracy

- 18 USC 371
- 18 USC 286
- 18 USC 287

HEALTH CARE FRAUD STATUTES

Mail and Wire Fraud

- 18 USC 1341, 1343
- Kickbacks 42 USC 1320A-7b
- False Statements 18 USC 1001

HIPAA STATUTES

Since 1996

- Federal Health Care Offense 18 USC 24
- Health Care Program 18 USC 24
- Health Care Fraud 18 USC 1347

We want you to be successful--
make money and follow the
law. Before the events overtake
you, talk to the agencies that
have the responsibility to
enforce the law.

CRIMINAL DIVISION VIEWS ON HEALTH CARE FRAUD

- “A company that does not have a compliance program is a little like conducting business without insurance.”
 - Assistant Attorney General Michael Chertoff of the Criminal Division.
- “Pharmaceutical fraud will continue to get the attention of Federal agencies.”
 - Deputy Assistant Attorney General Alice Fisher of the Criminal Division.
- <http://bna-pub2-bna.com/lnnpubs/hft.nsf>

FUTURE PHARMACEUTICAL CASES

- Medicare prescription drug benefit?
- Disgorgement-- United States v. Schering Plough
- Kickback cases-- TAP
- Extra label prescription drug promotion--
United States v. Genentech

FUTURE PHARMACEUTICAL CASES

- Pricing TAP
- Prescription Drug Marketing Act-- United States v. Rosen
- Adverse event reporting--United States v. Hiland, 909 F.d 1329 (8th Cir. 1990).
- Drug application process-- United States v. Marcus, 82 F.3d 606 (4th Cir. 1996).

Some factors we consider in deciding to pursue a case

- The Government Perspective
 - HHS PERSPECTIVE
 - FDA PERSPECTIVE
 - USAO
- Science . . . Health Policy
- Regulatory Enforcement Goals
- Nature of Violations-- Can they be explained to the fact finder, a jury?

Some factors we consider in deciding to pursue a case

- The history of the *putative* defendant
- The consequences of the violations, focusing on actual or potential threat to the public health and whether consumers or government agencies were harmed or defrauded.
- Had illegal conduct *ended before government intervention* and actions taken to ensure that it will not be repeated?

Some factors we consider in deciding to pursue a case

- What will be the deterrent value of the case, or, in simplest terms, what is the guideline sentencing?
- What are the DOJ priorities in terms of type of case?
- Can the defendant help the government to prosecute others?

What You Can Do?

- Opportunity to satisfy agency's concerns
- Opportunity to meet the goals of the investigation

Value of Civil and Criminal Enforcement

- Removal of violative products and practices from the marketplace
- Real deterrence from prosecution and conviction
- Efficient use of government resources
- Getting at the truth quickly
- Assistance using science and experts
- Credibility

Principles of Federal Prosecution of Corporations

- Corporate Compliance Policy
- The principles do recognize that the existence of an adequate and effective compliance program may be one of several relevant factors in determining whether to charge a corporation. What does this mean? What is an adequate and effective program?
- Sentencing guidelines