

KING & SPALDING

*National Medical Device Audioconference
Comparing, Contrasting and Complying with Global Codes of Conduct
November 10, 2008*

**Legal and Enforcement Issues:
An Overview of International Enforcement**

**John T. Bentivoglio
jbentivoglio@kslaw.com
202.626.5591**

Medical Device Companies

The Current Enforcement Environment

- Oversight and Enforcement in Europe
- Oversight and Enforcement in Developing Areas
- The Foreign Corrupt Practices Act
 - Recent Settlements
- Implications for Medical Device Manufacturers

Medical Device Companies Legal and Regulatory Risks

- International sales, marketing and promotional practices can create unique legal and regulatory risks.
- Many healthcare systems are operated and overseen by governmental agencies.
- Healthcare professionals frequently are government employees.
- Legal and regulatory risks for medical device companies vary widely based on national laws.

Enforcement -- Global

China

- The Beijing Health Bureau published a list of 21 pharmaceutical manufacturers found guilty of bribery. The companies on the list, which was published in late November 2007, will be barred from selling products to medical institutions in the city for two years.
- In August 2007, Beijing Yuandong De'er Medical Device Co. Ltd. was found guilty for offering bribes worth US \$200,000 to officials from 11 hospitals in the city from July 2002 to September 2006.
- In August 2006, Chinese authorities arrested two senior officials from Chongqing Chest Hospital for allegedly accepting improper payments from medical device supplies. Authorities alleged that the hospital purchased two respirators and one ultrasound machine from Chongqing Aikang Trading Co.

Enforcement -- Global

China

- China has pursued what may be a unique approach to reducing kickbacks to physicians. Authorities offered amnesty to physicians who returned improper payments, allowing physicians to put the money in bank accounts set up especially by China's health department. An estimated \$30 million in illegal kickbacks was returned during 2006. Chinese health departments investigated more than 2,500 cases of commercial medical bribes in 2006, involving an estimated \$75 million in illegal payments.

Enforcement -- Global

Croatia

- In November 2004, prosecutors in Croatia announced a probe of potentially improper payments by a pharmaceutical manufacturer to local doctors. As of February 2007, it was not clear whether the investigation was on going and/or whether the company or doctors would face formal charges.

Germany

- In 2004, state prosecutors in Munich confirmed that they searched the offices of a pharmaceutical manufacturer in connection with potential improper payments to physicians and hospitals. The raids were carried out and company facilities in Frankfurt and Darmstadt.

Enforcement -- Global

Italy

- In mid-June 2006, Italian authorities arrested three senior executives of Recordati -- Italy's largest pharmaceutical company -- on bribery charges. The Milan office of the country's financial police is leading the investigation. Among those taken into custody was the company's Pharmaceutical Division General Manager, Vittorio Bonazzi, who resigned after being arrested.

Russia

- The Russian Prosecutor General's office arrested Vitaly Smerdov, CEO of Russian pharmaceutical company Protek, in August 2007 on charges of giving bribes to officials in the Federal Mandatory Health Insurance Fund. Protek is Russia's largest pharmaceutical distributor, with 2006 revenue of more than US \$ 2 billion.

Enforcement -- Global

South Africa

In March 2007, South African police arrested and charged a senior Medicines Control Council official for attempting to solicit a bribe from a pharmaceutical company representative in exchange for expediting registration of the company's products.

The Netherlands

- In 2005, a Dutch agency ordered a U.S. pharma manufacturer to halt a post-market research study. According to authorities, participating doctors received €100 per enrolled patient for a free 3-year magazine prescription, but the protocol was vague, did not meet research quality standards, and lacked a clear research objective.

Enforcement -- Global

The Netherlands (cont'd)

- Dutch authorities placed a company on probation for violations of the country's Code on the Promotion of Medicinal Products. According to Dutch authorities, the company provided airfare and accommodation for doctors to attend a conference on bipolar disorder in Cannes, France.

Enforcement -- Global

Turkey

- Istanbul police raided a company's headquarters in Turkey in February 2005, taking 11 people into custody. The individuals included several top executives of the company's Turkish subsidiary. According to the local police, the individuals were arrested were charging excessive prices for certain pharmaceutical products.

United Kingdom

- In February 2006, the ABPI (U.K. pharmaceutical association) suspended a member company after finding that found a senior manager for the company gave improper payments to a doctor and other officials from a local hospital.

Enforcement -- FCPA

- 2002: U.S. radiopharmaceuticals concern, settled charges that its affiliates improperly paid physicians in Taiwan, Mexico, Belgium, Luxembourg, and France to persuade them to prescribe the company's product. U.S. parent company paid \$500,000 to settle; Taiwanese subsidiary paid \$2 million.
- 2004: Top 20 pharmaceuticals company paid \$500,000 to settle claims that it gave \$75,000 to a charity headed by a government official. That official was also in a position to direct some government pharmaceutical sales.

Enforcement -- FCPA

- 2005: U.S. medical device company, settled a \$450,000 FCPA claim related to alleged payments of \$105,000 to foreign physicians in a position to direct hospital purchases of the company's products.
- 2007: US-based manufacturer of blood transfusion instruments and its CEO settled SEC charges involving bribery allegations in Italy. The company agreed to enter into a cease-and-desist order with the SEC, and the CEO agreed to pay a civil penalty of \$30,000.

International Oversight and Enforcement

Self-Regulatory Codes of Conduct

- For most countries, offering bribes or other payments to influence prescribing or purchasing decisions is a crime.
- Regulatory oversight and enforcement of national laws varies greatly by country.
- There is greater interest from law enforcement and regulatory agencies in the relationships between manufacturers and healthcare professionals.
- Self-regulatory codes of conduct play an important role in governing relationships between manufacturers and healthcare professionals.

Biography -- John T. Bentivoglio

John Bentivoglio is a partner in the firm's Washington, D.C., office and serves as Co-Chair of the FDA/Healthcare Group. His practice focuses on assisting pharmaceutical, medical device, and biotechnology manufacturers in three broad areas: FDA and healthcare regulatory counseling, compliance program development and implementation, and representation of companies in civil and criminal investigations by federal and state law enforcement agencies. On the regulatory side, he advises companies on federal and state anti-kickback laws, FDA advertising and promotional rules, drug pricing and reporting, and Medicare reimbursement issues. He has assisted numerous companies in developing, implementing and assessing corporate compliance programs in line with U.S. Sentencing Commission and HHS Office of Inspector General Guidelines, and with state compliance program laws and regulations. And he has represented pharmaceutical and medical device manufacturers in investigations by U.S. Attorney's Offices in Massachusetts, New York, Maryland, Philadelphia, and California.

From 1997-2000, he served as Associate Deputy Attorney General and Special Counsel for Healthcare Fraud at the U.S. Department of Justice. In these capacities, he advised the Attorney General and Deputy Attorney General on national enforcement initiatives, healthcare investigation and prosecution policies, interagency coordination, and related issues. Earlier in his career, Mr. Bentivoglio served as a professional staff member to the Chairman of the U.S. Senate Committee on the Judiciary, where he handled criminal law and procedure, white-collar crime issues (including healthcare and financial fraud), and international crime and terrorism legislation.

jbentivoglio@kslaw.com
202.626.5591