Cooley

HEALTH CARE/LIFE SCIENCES REGULATORY

Summary: Health Care Fraud Investigation/Inquiry Experience

SELECT GOVERNMENT & QUI TAM INVESTIGATIONS/INQUIRIES

1. Defended a U.S-based global pharmaceutical manufacturer in a False Claims Act matter alleging best price violations related to an unrestricted educational grant provided to a managed care organization in return for formulary placement of a blockbuster cholesterol product. Representation included the negotiation of a civil settlement agreement with the U.S. Department of Justice, civil settlement agreements with state Medicaid Fraud Control Units, and a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General.

2. Defended a U.S-based global pharmaceutical manufacturer in a False Claims Act matter alleging off-label promotion of its pharmaceutical product that had an over 90% off-label market. Representation included the negotiation of a civil settlement agreement with the U.S. Department of Justice, civil settlement agreements with state Medicaid Fraud Control Units, and a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General.

3. Defended a U.S.-based global pharmaceutical manufacturer in a multi-year government investigation initiated by the U.S. Department of Justice related to the misbranding of a schedule II pharmaceutical product. Representation included the negotiation of a civil settlement agreement with the U.S. Department of Justice, civil settlement agreements with state Medicaid Fraud Control Units, and a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General. Matter involved exclusion of individual company executives.

4. Defended a foreign-based global pharmaceutical manufacturer in a False Claims Act action involving five *qui tam* complaints related to the sales, marketing and promotional activities for several drugs in the product portfolio. Criminal and civil investigators from multiple Federal agencies, including the FDA, Veterans Administration and FBI, were involved in the investigation. Matter included massive document collection, review and analysis; witness interviews; and cutting-edge legal issues. Negotiated a civil settlement agreement with the U.S. Department of Justice; settlement agreement and release with the lead *qui tam* relator; civil settlement agreements with the National Medicaid Fraud Control Unit team and individual states; and a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General. Continue to handle resolution of *qui tam* complaints and related matters.

5. Defended a foreign-based global pharmaceutical manufacturer in a False Claims Act *qui tam* action related to the sales, pricing and promotion of certain Medicare Part B prescription drug products. The civil action resulted in settlement and corporate integrity agreement. Negotiated state settlements with the National Medicaid Fraud Control Unit team and individual states. Represented company in subsequent civil *qui tam* action and negotiated an extension of the CIA the following year in connection with allegations related to different sales and marketing activities for different company products.

6. Civil and criminal defense of a U.S.-based global pharmaceutical manufacturer in a multi-year government investigation initiated by two U.S. Attorney's offices (Eastern District of Pennsylvania & District of Massachusetts) related to the sales, promotion and pricing of numerous pharmaceutical products to long term care facilities. No intervention.

7. Responded to HIPAA subpoenas issued by the U.S. Attorney's Office for the Eastern District of Pennsylvania in connection with alleged off-label marketing by a pharmaceutical manufacturer of several products during advisory boards and other promotional speaking activities. Subsequent subpoenas issued by one state for similar documents under the state False Claims Act. Client became a witness in these matters.

8. Defended a foreign-based global pharmaceutical manufacturer in a multi-jurisdiction (state and federal) government investigation of sales, marketing and research activities. Three state Medicaid Fraud Control Units led the civil and criminal investigation involving, among other items, retail interchange programs, MAC pricing, and FDA listing concerns. FDA and OPM were actively involved. Client was dismissed from False Claims Act *qui tam* action; intervention against co-promote partner only.
9. Negotiated a settlement with the Federal Trade Commission (FTC) related to a complaint challenging Fresenius Medical Care Ag & Co.'s proposed acquisition of an exclusive sublicense from Luitpold Pharmaceuticals, Inc. and Daiichi Sankyo, under which Fresenius would manufacture and supply the intravenous iron drug Venofer to dialysis clinics in the United States. The Department of Health and Human Services Office of Inspector General also was involved in the matter. Unique government program pricing issues involved in FTC settlement.
10. Negotiated a settlement with the New York Office of the Attorney General Medicaid Fraud Control Unit on behalf of a physician practice management company related to billing practices and revenue management services provided for a New York physician's group, in which the state alleged false claims were submitted to the state Medicaid program.
11. Defended a California-based skilled nursing facility in a False Claims Act matter alleging the submission of false claims for rehabilitation therapy provided by the facility's contracted rehabilitation therapy provider. Representation included the negotiation of a civil settlement agreement with the U.S. Department of Justice. No corporate integrity agreement was required by the Department of Health and Human Services Office of Inspector General.
12. Defended a pharmaceutical manufacturer in a False Claims Act matter involving allegations of misconduct under state supplemental rebate agreements and improper Medicaid Best Price reporting. Matter was resolved by the company in connection with its sale/change in ownership.
13. Assisting a foreign-based global pharmaceutical manufacturer with its defense of a California Department of Insurance investigation arising from alleged inappropriate payments to health care professionals and patient advocacy groups.
14. Defending a technology company in a government investigation by the Massachusetts Office of the Attorney General related to a contract awarded to its business partner for development of the state's health insurance exchange. Cutting-edge legal issues, including document collection from cloud-based electronic systems.
15. Defending a hospital system in connection with a congressional inquiry related to the use of a certain class of drugs.

SELECT INTERNAL INVESTIGATION MATTERS

1. Voluntary disclosure on behalf of a pharmaceutical manufacturer to applicable government agencies, including the FDA, Department of Justice and Department of Health and Human Services Office of Inspector General, in connection with certain customer relationships (managed care and specialty pharmacies) involving a large portfolio of drugs. Disclosure became part of a global civil and criminal settlement emanating from a False Claims Act *qui tam* action.
2. Voluntary disclosure on behalf of a medical device manufacturer to the Department of Health and Human Services Office of Inspector General following a robust internal investigation emanating from a hotline complaint to the Compliance Department and letters to the Board of Directors related to multiple years of inappropriate remuneration to a specific key opinion leader. Assisted company in defense of False Claims Act *qui tam* complaint filed simultaneously with the voluntary disclosure. Disclosure became part of a global civil and criminal settlement.
3. Conducted all phases of an internal investigation and assisted a company with a voluntary disclosure to applicable government agencies, including the FDA, in connection with a post-market study conducted outside the United States by a pharmaceutical manufacturer.
4. Voluntary disclosure on behalf of a foreign-based global pharmaceutical manufacturer to a State Attorney General, Health Care Fraud Division, regarding the fraudulent conduct by certain prescribers in connection with a patient assistance program.