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WHAT TO DO WHEN GOVERNMENT AGENTS ARE KNOCKING ON YOUR CORPORATION'S DOOR:

*Successfully Navigating
Government Investigations*

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I. INTRODUCTION.

A. A Changing Climate.

By 2002, corporate fraud allegations consumed innumerable headlines nationwide. Scandals at Tyco, WorldCom, Enron, Global Crossing, and others disturbed financial markets and threatened to undermine public confidence. The government has responded with bold new initiatives to combat corruption and restore confidence in the marketplace. In the face of this new and far-reaching government activity, corporations need to reassess their compliance plans to avoid investigation, and determine how best to respond should an investigation occur.

B. The Government's Response.

1. The Sarbanes-Oxley Act of 2002.

This legislation was the most wide-ranging reform of American business practices in decades. Signed by President Bush on July 30, 2002, the Act provided prosecutors and regulators with new avenues for ensuring corporate responsibility and restoring Americans' confidence in the market. Among its more significant reforms, the legislation:

- Created a new Accounting Oversight Board to police the practices of the accounting profession;
- Strengthened auditor independence rules;
- Increased the accountability of officers and directors;
- Enhanced the timeliness and quality of public companies' financial reports;
- Barred insiders from selling stock during blackout periods;
- Created a new securities fraud provision with a 25-year maximum term of imprisonment;
- Directed the Sentencing Commission to review sentencing in white collar crime, obstruction of justice, securities, accounting, and pension fund cases;
- Required CEOs and CFOs to personally certify that financial reports submitted to the SEC fully comply with the securities laws and fairly present, in all material respects, the financial condition of the company;
- Made it a crime to willfully certify any financial report known to be false or noncompliant, punishable by up to 20 years in prison;
- Criminalized the alteration or falsification of any document with intent to obstruct the investigation of any matter within the jurisdiction of a United States

- department or agency;
- Criminalized retaliatory conduct directed at corporate whistleblowers and others; and
- Required that audit papers be retained for 5 years and criminalized the failure to maintain such records.

2. The Corporate Task Force.

The Corporate Task Force was created on July 9, 2002, by Executive Order No. 13271. Its mission is to “strengthen the efforts of the Department of Justice and Federal, State and Local agencies to investigate and prosecute significant financial crimes, recover proceeds of such crimes, and ensure just and effective punishment.” A sweeping collection of agencies, investigators, and prosecutors from across the country, the Task Force is comprised of the following individuals:

- Director of the Federal Bureau of Investigation;
- Assistant Attorney General, Criminal Division (DOJ);
- Assistant Attorney General, Tax Division (DOJ);
- U.S. Attorney for the Central District of California;
- U.S. Attorney for the Northern District of California;
- U.S. Attorney for the Northern District of Illinois;
- U.S. Attorney for the Eastern District of New York;
- U.S. Attorney for the Southern District of New York;
- U.S. Attorney for the Eastern District of Pennsylvania;
- U.S. Attorney for the Southern District of Texas;
- Secretary of the Treasury;
- Secretary of Labor;
- Chairman of the Commodities Futures Trading Commission;
- Chairman of the Federal Communications Commission;
- Chairman of the Federal Energy Regulatory Commission;
- Chairman of the Securities and Exchange Commission;
- Chief Inspector of the U.S. Postal Inspection Service; and
- Director of the Office of Federal Housing Enterprise Oversight.

3. Amendments to the False Claims Act.

The False Claims Act was first passed in 1863 and made liable any individual or entity that knowingly defrauds the government. The Act has been periodically amended to meet the new demands and challenges of the changing corporate climate. The 1986 amendments to the Act reflect the changing climate of fraud actions:

- a. Defined “knowingly” to include “reckless disregard” or “deliberate ignorance,” thereby lowering the government’s burden for stating a claim;
- b. Increased per incident damages from double to treble damages, and increased the civil penalty.

The Act also empowers private individuals to bring fraud claims on behalf of the government, and it rewards such individuals when the suit is successful. Whistleblowers therefore have a strong incentive to bring a claim.

- a. Federal Whistleblower Statute for False Claims Act Violations – 31 U.S.C. § 3730.
 - i. Actions by Private Persons – “A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.” 31 U.S.C. § 3730(b)(1).
 - ii. Awards to *Qui Tam* Plaintiffs – “If the Government proceeds with an action brought by a person under subsection (b), such person shall . . . receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. . . . Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys’ fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.” 31 U.S.C. § 3730(d)(1) (emphasis added).

b. Whistleblower Financial Incentives

In 2003, the DOJ recovered \$1.48 billion under the False Claims Act from citizen-initiated suits alone. Whistleblowers, in return, received \$319 million. Some individual cases are demonstrative of the trend:

- i. June 2003 – HCA Inc. (Columbia/HCA) settled criminal and civil false claims actions for a record \$1.7 billion (the largest healthcare fraud settlement in U.S. history), of which the whistleblowers received a combined share of over \$150 million;
- ii. June 2003 – AstraZeneca Pharmaceuticals paid \$355 million to resolve allegations related to its prostate cancer drug, Zoladex, of which the whistleblower received \$47.5 million;
- iii. May 2004 – Pfizer settled fraud charges involving its Warner-Lambert unit for \$430 million, of which the whistleblower received \$26.6 million; and
- iv. July 2004 – Schering-Plough settled a civil claim for \$346 million, of which the three whistleblowers will receive a combined \$31.7 million.

C. The Results Are In: The Government's Success Thus Far.

Armed with the powerful new Sarbanes-Oxley Act, the Corporate Task Force has reported great success at stemming the tide of corporate fraud through criminal and civil investigations. The government netted more than \$8.8 billion in recoveries and restitution from its investigation and prosecution of U.S. corporations in 2003 alone. And this astounding figure does not include the more than \$360 million in corporate fines. The government's 2003 recovery represents an almost 100% increase from 2002 and, while the figures for 2004 are not yet final, the evidence suggests that these staggering numbers will continue to rise.

1. Criminal Actions.

On the criminal front, the Task Force reported that in just two years Justice Department prosecutors and regulatory Task Force members have:

- a. Obtained over 500 corporate fraud convictions or guilty pleas; and

- b. Charged over 900 defendants and over 60 corporate CEOs and presidents with some type of corporate fraud crime in connection with over 400 charged cases.

2. Civil Actions.

On the civil front, the SEC serves as the lead government agency in combating financial fraud. From July 2003 to July 2004, the SEC filed 614 civil enforcement actions, 143 of which involved financial fraud and issuer reporting actions. During that period, the Commodity Futures Trading Commission instituted 68 enforcement actions, and the Department of Housing and Urban Enterprise Oversight brought civil actions against Freddie Mac executives and negotiated with Freddie Mac a record \$125 million civil penalty for violations.

D. Effects on the Life Sciences Industry.

Because the government identified a high incidence of fraud in the life sciences industry, the industry was one of the first to feel the substantial force of Sarbanes-Oxley and Corporate Task Force investigations. According to the DOJ's Performance and Accountability Report for 2003, "as much as 10% of annual health care costs may be attributable to fraud." Additionally, "[f]raudulent claims submitted to health care insurers and medically unnecessary services performed simply to generate billings are prevalent in every geographical area in the country." Based on these findings, it is no surprise that the government has dedicated a great deal of its energy and resources to investigating potential fraud actions within the life sciences industry.

Not only is the government more committed than ever to discovering and correcting fraudulent activity within the life sciences industry, the DOJ's 2003 Performance and Accountability Report indicates that the tools at the government's disposal are increasingly sophisticated: "Enhanced use of technology to analyze health care billing data will allow law enforcement and health care program agencies to become more proactive in detecting fraud and abuse, identifying systemic weaknesses and closing loopholes in the system before criminals take further advantage of them."

Moreover, as indicated by the composition of the Corporate Task Force, healthcare fraud has become a major focus of U.S. Attorneys. Since 1986, the United States has recovered in excess of \$6 billion from over 400 suits. In 2002 alone, the government used the False Claims Act to extract the following recoveries from life sciences companies:

- \$586 million from TAP Pharmaceuticals;
- \$87.3 million from Pacificare Health Systems;
- \$76 million from General American Life Insurance;
- \$73.3 million from State of California and County of Los Angeles; and
- \$29 million from Lifemark Hospitals of Florida.

It is clear from these astounding numbers that the life sciences industry will not be spared from the government's close scrutiny. As a result, life sciences companies must keep pace with the growing labyrinth of regulations and develop effective compliance plans, or risk increased government intervention.

E. What To Do.

In the face of the changing climate, the growing number of government investigations, and the staggering volume of civil and criminal recoveries, corporations need to be increasingly attuned to how and why investigations happen. Every corporation should ask itself, "What can I do to avoid an investigation?" and "What should I do if an investigation occurs?" This paper answers these important questions and provides guidance on what to do when the government starts asking questions.

SELECTED BIOGRAPHIES

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Complex Civil Litigation
Intellectual Property, including Patent disputes
FCA/Qui Tam
Government Contractor Services

Practice Areas

Jacques Smith, a partner of the firm, specializes in the litigation of complex commercial matters. Jacques is an AV-rated attorney and an active member of the firm's Litigation, Life Science, Government Contractor Services and Intellectual Property Groups. He has amassed over a decade of experience handling jury, bench, and administrative trials in a variety of civil and criminal cases. He has handled a broad range of cases in mediation, arbitration, trial, and appeal in state and federal courts throughout the country. His principal litigation experience is in the areas of complex federal court litigation; intellectual property, including patent disputes; False Claims Act defense; and products liability issues.

Client Work

Jacques represents domestic, foreign, and sovereign clients in complex civil litigation at all levels in both federal and state courts. He also frequently advises these clients with respect to their rights and liabilities before litigation arises. He has substantial experience in handling and supervising a nationwide litigation docket of complex cases arising in multiple states. Over 50 of Jacques' cases have been reported.

Selected significant matters include:

- Achieved total victory on behalf of a vaccine manufacturer in a False Claims Act litigation. *Dingle v. BioPort Corp.* (W.D. Mich.; 6th Cir.; USSC).
- Victorious representation of a generic pharmaceutical company in a patent case where a Motion for Summary Judgment was granted allowing the generic company to market its generic version of a pioneer drug; Victory affirmed on appeal before the Federal Circuit. *Glaxo v. Impax Laboratories* (N.D.Cal.).
- Successfully represented a major foreign corporation in a patent dispute brought under Section 337 of the Tariff Act before the International Trade Commission. In *The Matter of Certain Zero-Mercury-Added Alkaline Batteries*. (ITC).
- Victorious representation of a major vaccine producer in a challenge brought by military service members. Motion to Dismiss granted. *Bates v. BioPort Corp.* (D.D.C.).

- Successfully intervened on behalf of multiple clients to assure that their confidential information was protected in federal court litigation, including:
- Protecting the confidential trade secrets of a major software company in *United States v. Oracle Corp.* (N.D. Cal.);
- Preserving the business secrets of a pharmaceutical manufacturer in *United States v. Philip Morris, Inc.* (D.D.C.); and
- Securing the confidentiality of important state documents for a sovereign nation in *In Re: Vitamin Antitrust Litigation* (D.D.C.).
- Successfully represented APA-The Engineered Wood Ass'n v. Professional Service Indus., Inc., (N.D. Ill) in claims of copyright infringement, passing off, and false advertising.
- Winning representation of a sovereign nation in a breach of contract action, prevailing on a Motion to Dismiss and winning attorneys' fees. *ABC v. Gabonese Republic.* (C.D. Cal.; 9th Cir.).
- Won a False Claims Act action on behalf of a hospital where its former General Counsel brought suit. In a case of first impression, Motion to Dismiss was granted and total victory was achieved. (Sup. Ct. Cal.; N.D. Cal.).
- Represented a major hospital in connection with a proposed Government audit and complex administrative subpoena; Case successfully resolved. (E.D. Pa.; 3d Cir.).
- Successfully represented an international computer company in connection with complex patent litigation; Summary judgment awarded at the trial court. (S.D.N.Y.).
- Represented a major pharmaceutical company in connection with patent and unfair competition litigation; Case successfully resolved.
- Representing a major utility company in wrongful death, wrongful injury, and product liability issues.

Previous Work

In 1990, Jacques began his career as a litigator while serving with the Judge Advocate General's Corps of the United States Navy. As a Naval attorney, Jacques served as a prosecutor, chief defense counsel, and appellate defense counsel while being stationed in locations throughout the world. He gained extensive litigation experience, trying hundreds of courts-martial at trial and on appeal. Jacques later served in the Navy's General Litigation Division representing the Navy's and Department of Defense's interests in Federal District Courts and Courts of Appeal throughout the country, the United States Court of Claims, and the Federal Circuit. Of significant note, since 1995 while representing the Navy in dozens of some of the most complex and challenging civil litigation matters throughout the country, Jacques has yet to lose a civil litigation matter—at trial or on appeal.

Publications/Presentations/Recognitions

Jacques is also committed to public service matters and in 2000 he was awarded the firm's Albert Arent Pro Bono Award for outstanding commitment to community service and pro bono interests. His public interest work is significant and varied including work for Catholic Charities, representation to the indigent, and a decade of service as an Instructor, Mentor, and Coach of the Benjamin Banneker Academic High School Moot Court Team in connection with Georgetown University Law School's Street Law Program.

Jacques was named the American Bar Association's Outstanding Young Naval Attorney in 1993 and has been awarded three Navy Commendation Medals, the Navy Achievement Medal, and multiple Secretarial and Flag Letters of Commendation for outstanding military and professional service. He was promoted to Commander in the United States Naval Reserve in 2004 and specializes in civil litigation before the federal courts on behalf of the Department of the Navy and United States Marine Corps.

Jacques is a regular speaker and commentator on litigation issues nationwide.

Bar and Court Admissions

District of Columbia Bar

Maryland Bar

Louisiana Bar

U.S. Supreme Court

U.S. Court of Appeals for the Federal Circuit, the District of Columbia Circuit, and the Third, Fourth, Sixth, and Ninth Circuits U.S. Court of Federal Claims

U.S. District Courts for the Districts of the District of Columbia, Maryland, Western District of Michigan, Eastern District of Louisiana, and the Eastern District of Wisconsin

U.S. Court of Appeals for the Armed Forces

Navy-Marine Corps Court of Criminal Appeals

United States Court of International Trade

Education

Louisiana State University, J.D. 1991

Trial Advocacy Institute, University of Virginia 1998

Loyola University, B.A. (cum laude) 1988

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Practice Areas

John Nassikas is a partner at Arent Fox in the firm's Litigation Department. As the Life Sciences Group co-leader and head of the firm's national white-collar defense and government investigations practice group, John concentrates on complex criminal and civil litigations and internal corporate investigations.

Client Work

John represents individuals, national and international corporations, and foreign governments in both litigation and business matters. He has defended many pharmaceutical and medical device companies and health care providers and their employees in significant federal and state investigations throughout the country.

John has extensive experience in federal grand jury practice and trial work both as a former federal prosecutor and as a defense attorney. He deals regularly with United States Attorney Offices and the U.S. Department of Justice on an array of matters, including health care, government contracts, immigration and financial fraud investigations, money laundering, and international conspiracies.

In August 2003, the United States District Court for the Eastern District of Virginia appointed John to serve as counsel for the lead defendant in the high-profile federal prosecution of the "Virginia Jihad Network."

Previous Work

Before joining Arent Fox, John was an Assistant United States Attorney for the Eastern District of Virginia. As an Assistant United States Attorney in the Criminal Division, from 1991 to 1995, he was responsible for major felony prosecutions, from grand jury through trial and appeal, in areas including financial, telecommunications, and government contracts fraud, violent crime, organized crime, and narcotics trafficking.

Before his appointment to the U.S. Attorney's Office, John was a litigator at a Washington, D.C. law firm.

Professional Activities

John is the current chairman of the Criminal Law Committee of the District of Columbia Bar Association.

Publications/Presentations/Recognitions

John has been a speaker at the ABA Health Care Fraud Conference, the IIR Clinical Research Conference, and the ACI Medical Device Conference. He has been a visiting law school lecturer on criminal law and the Internet and an instructor of Continuing Legal Education courses at the Federal Bar Association and elsewhere on corporate criminal law topics. John has also written on the international aspects of criminal defense work.

Specifically, John's recent speaking engagements include:

- Speaker, ACI Conference on "Reducing Legal Risks in Sales and Marketing of Medical Devices," November 2003.
- Speaker, "Criminal Risk in Clinical Research: Minimizing Liability," August 2003.
- Panelist and Presenter, Federal Bar Association CLE Program, "When Government Agents Knock on the Company Door," May 2001.

Bar and Court Admissions

District of Columbia Bar

Virginia Bar

U.S. Supreme Court

U.S. Courts of Appeals for the Fourth Circuit and District of Columbia Circuit

U.S. District Courts for the District of Columbia, the District of Maryland and the Eastern District of Virginia

Education

University of Virginia, J.D. 1984

Yale University, B.A. (magna cum laude) 1981