

# Research Organizations: Whistleblowers and False Claims Act Prosecutions

Presented to  
Medical Research Summit  
Washington, DC

Christopher Myers  
HOLLAND & KNIGHT LLP  
March 19, 2001

© HOLLAND & KNIGHT LLP

*"Let the message be very, very clear. We have made health care fraud a priority and we will pursue it as vigorously as we can."*

— Janet Reno

Attorney General of the United States, 1993

# HEALTH CARE FRAUD, WASTE AND ABUSE IS A TOP FEDERAL AND STATE ENFORCEMENT PRIORITY

- Department of Justice
- HHS
- HCFA
- HHS OIG
- FBI
- U.S. Attorney's Office
- State Medicaid Fraud Units
- Fiscal Intermediaries and Carriers
- Private Fraud Contractors

*“It is not the Department of Justice’s policy to punish honest billing mistakes... or mere negligence. But where there is reckless disregard and people go beyond simple negligence, I will use the law.”*

— Janet Reno

Attorney General of the United States, 1993

# CURRENT GOVERNMENT ANTI-FRAUD INITIATIVES

- Health Care Fraud a top priority of the Department of Justice
- Civil health care fraud matters at DOJ have increased from 270 in fiscal year 1992 to more than 4000 in fiscal year 1997
- HHS and DOJ recovered more than \$717 million in health care fraud, waste and abuse payments just for fiscal year 2000.
- Whistleblower payments totaled more than \$90 million.

# ***QUI TAM* SUITS**

## **Under the False Claims Act**

- Whistleblower suits alleging health care fraud under the *qui tam* provisions of the False Claims Act increased from 17 in 1992 to almost 300 in 1998.
- Estimates of as many as 4,000 additional whistleblower suits in the pipeline.

# FALSE CLAIMS ACT

## *Basis for Liability*

1. Submission of "claim for payment" to the federal government;
2. The claim is "false" or "fraudulent;" and
3. The defendant acted "knowingly."

# “KNOWINGLY” MEANS:

1. Actual knowledge;
2. Acts in deliberate ignorance of the truth or falsity of the information; or
3. Acts in reckless disregard of the truth or falsity.



# FALSE CLAIMS ACT DAMAGES:

1. Triple the amount of damages suffered by the United States

*PLUS*

2. A civil forfeiture of between \$5,000 and \$10,000 *per false claim*
  - Damages can be reduced in some cases from triple to double

# *QUI TAM* SUITS

## Under the False Claims Act

- Private Attorneys General or “Whistleblowers”
- Encourages people to report fraud to the government
- Reward to the *qui tam* plaintiff is that he or she will receive a percentage of the fraud recovery

# QUI TAM PROCEDURE

- *Qui tam* plaintiff or “relator” files suit in federal court under seal
- Government has sixty days (more with extensions) to review complaint and investigate
- Government *intervenes* or *declines*
- Case is then unsealed

# *QUI TAM* PROCEDURE

## If Government Intervenes:

- Government takes over and litigates the case
- *Qui tam* relator collects 15-25 percent of any judgment or settlement proceeds

# Research Institutions and Companies in the Crosshairs

Government investigators and whistleblowers are focusing more and more on research issues.

# Many Areas of Potential Liability

- Conflicts of interest/tainted research
- Fraud in obtaining federal grants
- False statements and certifications
- Failure to disclose funding from other sources
- Failure to accurately report results
- Billing Medicare for services to clinical trial patients

# Many Areas of Potential Liability (Cont'd)

- Cost Report Fraud
- Kickbacks
  - referrals for prescriptions
- Follow-up studies
- Inaccurate reporting of results
- Failure to report adverse reactions

# KICKBACKS AS FALSE CLAIMS

In a significant expansion of potential False Claims Act liability, several cases have asserted that claims not containing false information or representations, may nevertheless violate the False Claims Act if:

- The financial arrangements included in the claim violate the anti-kickback statute
- There is a false certification of compliance with the anti-kickback statute included in the claim



# *Qui Tam* Suits Against Research Institutions

- *Vermont Agency of Natural Resources v. United States*
- *United States ex rel. Berge v. Bd. Of Trustees of Univ. of Alabama* (NIH grant)
- *United States ex rel. Cantekin v. University of Pittsburgh* (NIH grant)

# Suits Against State Institutions Under the FCA

- The Supreme Court has held that the states are not “persons” for purposes of the FCA. *Vermont Agency of Natural Resources v. United States*.
- Thus, the states, their agencies, and presumably state institutions such as colleges and universities (to the extent they are state actors), are not subject to suit under the FCA.

# *United States, Ex Rel. Berge v. The Board of Trustees of the University of Alabama*

- Doctoral student alleged that the University and its faculty had made false statements in the annual progress report submitted to NIH.
- The jury found in favor of Plaintiff after a 10 day trial and awarded \$550,000, which was trebled under the Act to \$1.65 million. The jury also found for Plaintiff on state law claims, awarding \$50,000 in compensatory and \$215,000 in punitive damages.
- The verdict was reversed only after appeal.

# Allegations in *Berge*

The Plaintiff in *Berge* alleged false statements in the annual progress reports submitted to NIH. These included:

- (1) misrepresenting the amount of data that had been computerized under the program,
- (2) failure to attribute certain work to the student in the report, and
- (3) including plagiarized work in the report.

## Results in *Berge*

In *Berge* Plaintiff's theory of liability was not rejected.

Only the Plaintiff's utter lack of factual basis resulted in dismissal.

# *United States Ex Rel. Cantekin v. Univ. Of Pittsburgh*

- Professor did not reveal private funding by drug companies whose products were the subject of the study for which he submitted a grant application.
- Appeals court permitted suit to go forward because facts were in dispute as to whether professor knowingly submitted a false application.

# Settlement in *United States v. Thomas Jefferson University*

- In June 2000, the Dept. of Justice reached a global settlement with Thomas Jefferson University and several faculty members, resolving allegations under the False Claims Act for alleged fraud in relation to grants from the National Cancer Institute and the National Institute of Allergy and Infectious Diseases of NIH.
- The University agreed to pay \$2.6 million to resolve the case.
- Some of the allegations were initially raised in a *qui tam* suit filed by a former post-doctoral researcher.

# Settlement in *United States v. Thomas Jefferson University (con't)*

The alleged false claims included:

- submitting an application listing a Principal Investigator (PI) who had resigned from the University and had returned to his home in Italy
- reporting that the PI was in the U.S. performing work on the grant when he was in Italy
- using false or fabricated research data in several publications that were then used to obtain grant monies.



# Statements of the Prosecutor in the *Thomas Jefferson Case*

- "Federal research grant funds are not to be considered 'entitlements' and educational institutions are not free to spend to them as they deem appropriate."
- "The conditions attached to the award of a federal grant are vitally important to the government."

# Statements of the Prosecutor in *Thomas Jefferson* (Cont'd)

- "It is a call to adopt policies and procedures that closely monitor grant administration including cost transfers, cost allocation, expenditure of funds and oversight of who is actually performing the research. Most importantly, truthful communication with the government is an absolute imperative."
- "We simply cannot take the risk that false and/or fabricated data will be used in clinical trials on human subjects or that millions in grant funds are being improperly utilized."

# Statements of the Prosecutor in *Thomas Jefferson* (Cont'd)

- "Research that is done so carelessly that the data are meaningless, yet are reported to the government in such a fashion as to ensure continued federal funding, may also constitute fraud that will be punished through criminal and civil prosecutions by the government."

Sponsored Research: *Enforcement Efforts Increased*, David R. Hoffman, Assistant U.S. Attorney

# Lessons Learned From *Berge*, *Cantekin* and *Thomas Jefferson*

- *Qui Tam* suits often spring from disgruntled or marginalized persons in the organization - *e.g.*, the doctoral student or fellow researcher who has had a falling out or doesn't get along with the research team.
- Failure by program management to monitor and enforce federal reporting and other program requirements can leave the organization open to *qui tam* suits.
- One of the best ways to detect and prevent a *qui tam* suit is an effective compliance program.

# Increased Scrutiny of Research Programs Likely in the Future

# Department of Health and Human Services and NIH to Increase Monitoring of Grant Programs

In May 2000, the GAO recommended that HHS and NIH increase scientific and financial monitoring of grantees under NIH's grant programs.

*NIH RESEARCH - Improvements Needed in Monitoring Extramural Grants, GAO, May 2000*

# Department of Health and Human Services and NIH to Increase Monitoring of Grant Programs

GAO's recommendations were largely accepted by HHS and NIH and included:

- increased documentation of grantees' scientific progress before additional funding is awarded
- ensuring regular submission by grantees of single audit reports of their program
- development of procedures for more active use by NIH of the single audit reports

# ROLE OF COMPLIANCE PROGRAMS IN PREVENTING *QUI TAM* SUITS



# BENEFITS OF A CORPORATE COMPLIANCE PROGRAM

1. Reduces Likelihood of Criminal and Civil Liability
2. Provides Real Picture of Institutions Operations
3. Provides Structure to Disseminate Policy Changes Beyond Top Management.
4. Helps Preserve Confidentiality of Documents and Communications.
5. Dramatic Reductions in Penalties in the Event of Criminal Convictions.
6. Compliance Plan Creation and Implementation are Tax Deductible; Fines are Not.

# FEDERAL SENTENCING GUIDELINES

1991 Sentencing Guidelines for Organizations:

1. Remove judicial discretion to be lenient.
2. Restitution Mandatory - not credited against fine.
3. Penalties include restitution, fines and probation

# FEDERAL SENTENCING GUIDELINES

- Take into account whether a Corporate Compliance Program exists
- Organization's culpability lessened if an EFFECTIVE compliance program in place

# FINES

- Base Fine - Reflects seriousness of offense, *i.e.*, monetary loss or gain.
- Multiply by “culpability score” (steps taken before the offense to prevent and detect criminal conduct)
- Culpability score begins at 5
- Raised or lowered based on mitigating or aggravating factors

# MITIGATING FACTORS

- Compliance program  
“Effective Program to prevent and detect crime” (3 points)
- Other Mitigating Factors (Possible 5 Points)
  1. Whether organization reported offense
  2. Whether organization cooperated in investigation
  3. Whether organization recognized and accepted responsibility for conduct?

# AGGRAVATING FACTORS

- “Willful Ignorance”

Failure to investigate possible unlawful conduct under circumstances that would lead a reasonable person to investigate

- No Compliance Program

- Probation must be ordered

- Compliance Program imposed

- Complicity of Senior Officials

# *In Re: Caremark International, Inc.* Derivative Litigation

- Corporate Directors/Trustees and Officers can be held *personally* liable for failing to implement a compliance program
- Knowledge or suspicion of unlawful activity is *not* required
- U.S. Sentencing Guidelines incentives and massive potential liability require compliance and monitoring program

# Fiduciary Duty of Trustee/Board of Directors

- Fiduciary Obligation -- act in good faith, as an ordinary and prudent person (F.S. 617.0830)
- Conduct -- as an example for employees, set an ethical tone
- Inform itself of relevant facts -- rely upon officers, legal
- Annually approve Code of Conduct/Compliance Plan



# Speech By Lewis Morris Of OIG

Emphasis on “Effectiveness” of  
Compliance Program

# What Are the Factors of “Effectiveness”

- Compliance policies easily understandable - staff comprehension?
- Recurring compliance problems - management buy-in?
- Compliance officer accomplished mission - adequate resources, staff, and authority?
- Conflicting roles of compliance officer:
  - Auditor, risk manager, human resource manager, chief financial officer
  - "Do the right thing or do the profitable thing?"

# What Are the Factors of “Effectiveness” (Cont’d)

- Training to support compliance program
  - Staff, physicians, and contractors.
  - Code of conduct to contractors.
- Communications about Compliance Matters
- Recurrence and Type of Disciplinary Action
  - Range from verbal or written reprimands to dismissal.
  - Even-handed application of standards.
- Discovering Mistakes
  - Effective resolution.
  - Corrective action plan before problem discovered.
  - Repayment and/or voluntary disclosure.

# COMPLIANCE PROGRAM OPERATIONS

How do you know what areas to evaluate?

Guidance From Several Sources

- HCFA
- OIG Work Plan
- OIG Compliance Guidance
- Fraud Alerts
- NIH guidance