The False Claims Act

Litigating Scientific Misconduct

SUSAN E. SHERMAN, MHS JD

On May 16, 1995, the U.S. District Court for the District of Maryland ordered the University of Alabama at Birmingham to pay nearly $2 million to the Federal Government and to Dr. Pamela Berge, a former graduate student who had conducted research at the University, because the University violated the Federal False Claims Act *(1)* by failing to credit Dr. Berge and failing to accurately report her work in grant applications to the National Institutes of Health (NIH) of the Public Health Service (PHS) *(2)*. This is the first case in which a trial court has determined that an institution and its researchers are legally liable under the False Claims Act for the integrity of research conducted under a grant funded by the PHS. Previously, Federal scientific misconduct investigations have focused on the individual researcher's responsibility for scientific misconduct.

In 1987, Dr. Berge, then a Cornell University graduate student, conducted research for her doctoral dissertation at the University of Alabama at Birmingham on transmission of cytomegalovirus (CMV), looking particularly at mothers with recurrent CMV. She conducted her research with Drs. Sergio Stagno, Charles Alford, and Robert Pass, who had been conducting research on perinatal infections under an NIH grant since 1976. To conduct her research, Dr. Berge used data maintained by the University and data that she collected and computerized. The University agreed to provide up to $7,000 in grant funds to support data entry for Dr. Berge's project.

After finishing her research at the University of Alabama, Dr. Berge returned to Cornell to complete her doctoral work and in 1989 sent a copy of her dissertation and an abstract of a paper describing her research to the University of Alabama researchers. Dr. Berge's thesis findings were that infants born with CMV infection tended to be of low birth weight and short crown-heel length and that mothers who transmitted CMV to their infants more likely to have poor nutritional status, which suggested that maternal nutritional factors were related to transmitting CMV to the fetus. While attending a meeting of the Society for Epidemiologic Research in June, 1990, Dr. Berge heard Dr. Karen Fowler, another graduate student at the University of Alabama, present research results that she believed were taken from her dissertation without attribution.

Dr. Berge first attempted to resolve her concerns directly with Drs. Pass, Alford, and Stagno, and then with the University, filing scientific misconduct allegations against Drs. Pass, Stagno, Alford, and Fowler. After an initial inquiry into the allegations, the University decided that they did not merit further investigation, and reported this to the PHS. In 1993, Dr. Berge filed a False Claims Act complaint against the University and Drs. Pass, Stagno, Alford, and Fowler, alleging that they violated the False Claims act by submitting grant applications and progress reports to the NIH that included the abstract of her paper she had sent to them without acknowledging her, and described work that Dr. Fowler plagiarized from her dissertation.

The False Claims Act

The False Claims Act provides that any person who knowingly presents a false or fraudulent claim for payment to an officer or employee of the United States Government, knowingly makes or uses a false record or false statement to get a false claim paid or approved by the United States, or conspires to defraud the Government to get a false claim paid, is liable to the United States for up to three times the amount of monetary damages that the Government sustains because of the false claim, plus a civil penalty of $5,000 to $10,000 for each false claim *(1)*. "Person" may include an institution or organization. "Knowingly" means with actual knowledge or information or deliberate ignorance or reckless disregard of the truth or falsity of the information. No specific intent to defraud the Government is required. A "false claim" is any request or demand for money or property made to the United States or to a contractor, grantee, or other recipient if the Government provides or will reimburse any portion of the funds claimed *(1)*.

Anyone who has knowledge that leads him or her to believe that a recipient of Federal funds has violated the False Claims Act may bring a civil action on behalf of himself or herself and on behalf of the United States. In such a case, the individual is called the relator and the suit is called a *qui tam* case, meaning an action brought by an individual "who as well" sues on behalf of the Government. The Government may also bring an action under the False Claims Act without a relator.

A relator must file his or her False Claims Act complaint under seal, meaning that the complaint is kept confidential by the court until it is reviewed by the Attorney General of the United States *(3)*. The complaint must be filed within six years of the alleged violation, or within three years of when the Department of Justice becomes aware of the matter *(4)*. The Attorney General has sixty days (or more, if extended by the court) to review the allegations and evidence provided by the relator to assess

whether to intervene in, and take over, the action. The Attorney General will decide whether to intervene based on an assessment of the merits of the case and recommendations of the agency that awarded the funds. During the Attorney General's review of the case, the complaint is kept under seal and not provided to the defendant *(3)*.

If the Attorney General decides to pursue a case, the Government takes primary responsibility for prosecuting the case, and the relator may continue as a party, subject to certain limitations. If the Attorney General declines to intervene in a case, the relator may independently litigate the case. After the Attorney General decides whether to intervene, the complaint is unsealed and served on the Defendant.

Because a *qui tam* suit is brought on behalf of the Government, the Government is entitled to the majority of any monetary damages awarded, and additional compensation for legal fees and reasonable expenses *(3)* whether or not it intervenes in the case. If the Government prosecutes a case, the relator is usually entitled to 15–25 percent of the damages awarded, and the Government receives 75–85 percent of the damages. If the Government does not intervene, the relator is generally awarded 25–30 percent of the damages.

The Berge Case and Other False Claims Act Cases Based on Scientific Misconduct Allegations

Dr. Berge pursued her claims independently after the Government declined to intervene. At trial, Dr. Berge alleged that the University of Alabama and its researchers violated the False Claims Act by submitting grant applications and progress reports to the NIH from 1987 through 1992 that (a) asserted that a greater amount of data had been computerized than actually had been accomplished; (b) reported Dr. Berge's work without acknowledging her, thereby incorrectly implying that the University researchers conducted the work; (c) failed to disclose Dr. Berge's research results fully, thereby submerging findings that contradicted statements made in the University research proposals, and (d) described work that Dr. Fowler plagiarized from Dr. Berge.

First, the University stated in the 11th year grant application in 1987 that a vast amount of longitudinal data on chronic perinatal infections had accumulated and had been transferred to unified computerization in the previous three years. Dr. Berge argued at trial that this statement was false because when she arrived at the University in late 1987, she found that she had to unify and computerize nearly all of the data she used for her dissertation research from data located in the Obstetrics, Pediatrics, and Biostatistics departments within the University, from county medical records, and from medical records at a local hospital, and she had to add control subjects to the database.

Second, the progress report submitted by the University in 1988 included an abstract prepared by Dr. Berge describing her dissertation research on CMV but failed to acknowledge Dr. Berge or state that she was a graduate student at Cornell University. Dr. Berge argued that the progress report misrepresented that her work had been conducted by Alabama researchers.

Third, in the progress reports for 1989 and 1990, the University acknowledged Dr. Berge but failed to describe and analyze fully her research finding that a significant number of children born of mothers with recurrent CMV have recurrent and unknown CMV with sequelae, which has implications for vaccine development. Dr. Berge argued that the University submerged this finding because it contradicted University findings that children of mothers with recurrent CMV infection rarely have significant sequelae.

Fourth, the University progress reports for 1990 and 1991 and the grant renewal application for 1992 described research on CMV transmission and sexually transmitted diseases that Dr. Berge claimed Dr. Fowler plagiarized from her work. Dr. Fowler used the same statistical methodologies Dr. Berge had used in her dissertation and examined data on infant birth weight, crown-heel length, and head circumference that Dr. Berge said she had gathered.

The University of Alabama contested each of Dr. Berge's claims. First, the University argued that critical data had been computerized by the eleventh year grant application and that data computerization was ongoing, so that the statement in the 11th year grant application was correct. Second, the University argued that Dr. Stagno's failure to acknowledge Dr. Berge in the 1988 progress report was an oversight which he corrected in later progress reports. Third, the University claimed that it reported all of Dr. Berge's findings in progress reports for 1989 and 1990 and did not submerge her results. And, finally, the University asserted that Dr. Fowler had conducted all of her own research.

At the close of the trial, the jury found in favor of Dr. Berge and the United States, and the court ordered the University to pay Dr. Berge and the United States $1,650,000 (three times $550,000, the amount of damages incurred to the Government) and civil penalties of $10,000; with 30% of the total to be paid to Dr. Berge. The jury also awarded Dr. Berge $265,000 in damages for her claims under state law that her intellectual property had been stolen by the University investigators *(2)*. Neither the jury verdict nor the court's judgment identified which of the University's statements to the NIH violated the False Claims Act.

Therefore, it is not clear whether the jury decided that one, two, or more of the University's statements constituted false claims.

The University of Alabama appealed the District Court decision to the U.S. Court of Appeals for the 4th Circuit on September 21, 1995, after its motion for a new trial was denied by the U.S. District Court.

The Berge case is the first False Claims Act case based on scientific misconduct allegations that has been brought to a jury trial by a relator. The case is notable, first, in that the jury found that the University was liable under the False Claims Act for the truth of statements by University researchers in a grant application. While the jury found that the individual researchers violated the False Claims Act, it did not find the individuals liable for monetary damages. Second, the false claims identified by Dr. Berge largely related to inadequate attribution and description of work rather than to falsified or fabricated data. Third, because the University of Alabama conducted a scientific misconduct inquiry into the matter and determined that further investigation was not necessary, the PHS never formally investigated Dr. Berge's allegations.

A few other scientific misconduct cases have been brought under the False Claims Act based on descriptions of scientific research grant applications and progress reports submitted to the NIH. One such case, filed by Dr. Erdem Cantekin against the University of Pittsburgh, the Children's Hospital of Pittsburgh, and Dr. Charles D. Bluestone, in which Dr. Cantekin argues that Dr. Bluestone submitted false data and failed to report funding from other sources for his research in grant applications to NIH, is currently being litigated independently by Dr. Cantekin *(5)*.

A second case, filed by J. Thomas Condie against the University of California, the University of Utah, and Dr. John L. Ninnemann, in which Mr. Condie alleged that Dr. Ninnemann had fabricated and falsified results on burn trauma research reported in grant applications and progress reports to NIH, was pursued by the Government with the assistance of the relator, and was settled by the Government for $1,575,000 in August 1994 *(6)*. In this case, the PHS Office of Research Integrity (ORI) negotiated a separate settlement of scientific misconduct charges against Dr. Ninnemann on behalf of PHS based on findings made during litigation *(7)*.

A third case, filed and litigated independently by Dr. Kathryn Milam against the University of California, the M.D. Anderson Cancer Center, and Dr. Charles B. Wilson, Dr. Laurence J. Marton, Dr. Dennis F. Deen, Dr. Burt G. Feuerstein, and Dr. Philip J. Tofilon, was resolved in favor of the defendants by the U.S. District Court for the District of Maryland on October 6, 1995 on the basis of motions filed by the parties prior to trial *(8)*. In that case, Dr. Milam alleged that the defendants submitted false claims in grant applications to NIH by reporting results of research conducted by Dr. Tofilon that she claimed were false because she was unable to replicate them. The U.S. District Court found that there was insufficient evidence to show that Dr. Tofilon's data were false, despite Dr. Milam's inability to replicate them.

The court in the Milam case made several conclusions that may impact other scientific misconduct False Claims Act cases, including the Berge appeal.

First, the court found that statements made by researchers cannot be false if they are literally true. For example, the researchers' statement that they observed an increase in DNA cross-links in brain tumor cells after exposure to the drug Difluoromethylornithine (DFMO) is true, even though Dr. Milam observed a 30-percent increase while Dr. Tafilon reported a 93-percent increase.

The court also found that false claims could not be based on failure to describe aspects of the research that the defendants were not required by law to describe. For example, the defendants' failure to describe initial problems with replicating Dr. Tofilon's results was not a false statement because there was no statutory or fiduciary obligation to make this disclosure to the Government.

Finally, the court ruled that the report issued by ORI may be considered as relevant and highly probative evidence of whether a person committed scientific misconduct *(8)*.

PHS Administrative Procedures for Dealing with Scientific Misconduct Allegations

Traditionally, scientific misconduct allegations have been handled administratively by PHS which has formal administrative procedures *(9, 10)*. Further, any institution that applies for PHS funds is required by Federal regulation to have its own administrative procedures for handing scientific misconduct, and to assure the PHS, as a condition of funding, that it will comply with the PHS administrative procedures and its own administrative procedures *(11)*.

Under PHS procedures, when an individual complainant alleges that a researcher committed scientific misconduct, the PHS ORI or the researcher's institution will review the allegation to determine if it falls within the PHS's jurisdiction and the Federal definition of scientific misconduct. If it does, the institution or the ORI will notify the researcher that an allegation has been filed against him or her and then conduct an initial inquiry—and, if necessary, an investigation—into the allegation *(10, 11)*. The researcher who is the subject will be notified of the institution's or ORI's findings. An institution which conducts an inquiry or investigation must report its findings to the ORI, which may accept the

institution's findings, request additional information, or conduct its own investigation to make a PHS finding on the alleged scientific misconduct.

When ORI finds that an individual has committed scientific misconduct, that individual may request a *de novo* hearing before a Research Integrity Adjudication Panel of the Departmental Appeals Board of the Department of Health and Human Services (HHS), in which the Board considers the allegations anew *(10)*. If there is a hearing, the Departmental Appeals Board makes the final decision on whether a researcher committed scientific misconduct. The Departmental Appeals Board will also decide whether to impose remedies or sanctions recommended by the PHS. If PHS recommends debarment (prohibition from receiving any Federal funds for a period of years), the HHS Debarment Official may make this decision based on the Departmental Appeals Board findings.

There is currently no requirement that a complainant exhaust PHS administrative procedures prior to filing a False Claims Act case. The relator may file a civil action with the Attorney General instead of, in addition to, or after making scientific misconduct allegations to his or her institution or PHS. Administrative findings by an institution or PHS do not preclude addressing the same allegations in a False Claims action.

Litigation versus Administrative Resolution of Scientific Misconduct Allegations

There are several key differences between litigating a False Claims Act lawsuit and pursuing allegations of scientific misconduct through PHS administrative procedures.

Litigation is filed against the institution and the individual, while PHS procedures are pursued against only the individual. A False Claims Action is generally filed against both the institution and the individual because, under HHS grants administration regulations *(12)*, the institution is the grant recipient and is responsible for handling all funds awarded for a project and certifying under penalty of law that the project is conducted in accordance with all applicable Federal statutes, regulations, and policies *(13)*. The institution is also responsible for the conduct of the project under the legal theory of *respondeat superior*, which provides that an employer may be liable for the acts of its employees. The principal investigator is responsible for the scientific and technical direction of the project, and must certify that he or she will accept that responsibility and provide required progress reports on work conducted under the grant *(12, 13)*. Therefore, both the institution and the individual are responsible for ensuring that research is properly conducted under the grant and that Federal funds are not misused, and both may be held liable for false claims and statements regarding this work in a grant application or progress report.

On the other hand, a scientific misconduct investigation is conducted by the researcher's institution or the ORI to evaluate whether a researcher, not his or her institution, committed scientific misconduct.

The litigation standard for evaluating a claim is whether it is a false claim, while the PHS standard for evaluating an allegation is whether it is scientific misconduct. A False Claims Act case asserts that the institution and individual knowingly made a false claim to the Government, that is, made a false claim with actual knowledge or information or deliberate ignorance or disregard of the truth or falsity of the claim *(1)*. The false claim may be a statement in any part of a grant application, progress report, or other document submitted to the Government, including graphs and tables, descriptions of research results, and citations to prior work.

A scientific misconduct investigation evaluates whether the individual fabricated or falsified data, committed plagiarism, or conducted any other practice that seriously deviates from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research, which cannot be attributed to honest error or honest differences in interpretations or judgements of data *(10, 11)*. The HHS Departmental Appeals Board has indicated that an individual must intentionally engage in scientific misconduct (14). The alleged scientific misconduct must relate to a project for which the institution applied for or received PHS funding, but it does not have to be in the form of a statement made in a document submitted to the Government. Statements that constitute scientific misconduct may be found in laboratory notebooks or in published work supported by the PHS but not submitted to the Government.

A court could find that a false claim had been made to the Government in a situation in which PHS would not find scientific misconduct. For example, Dr. Berge argued that University of Alabama investigators did not accurately describe the level of computerization of their data, did not properly attribute her work in grant applications and progress reports to the NIH, and did not fully describe and analyze her work. While the jury may have found that these statements constituted false claims under the False Claims Act, PHS would not necessarily find that all of these statements constitute scientific misconduct. Dr. Berge did not allege that the University fabricated or falsified any of the computerized data, or misrepresented their research results. And while plagiarism is within the definition of sci-

entific misconduct, disputes over acknowledgement of work between collaborators falls outside the definition of scientific misconduct *(15)*. Conversely, PHS could make a finding of scientific misconduct that would not constitute a false claim to the Government. For example, if a researcher falsified data in a laboratory report that was not connected in any way with any document submitted to the Government, the relator might not be able to relate this misconduct to a false claim.

Litigation allegations are evaluated by a judge and jury, while scientific misconduct allegations are evaluated by scientific peers and administrators with expertise in scientific misconduct issues. In a False Claims Act case, the members of a jury are selected from the general public, who may view a claim differently than scientists. In a jury trial, the Government, the relator, or the defendants may have to provide expert witnesses to explain scientific methods, ideas, and practices to the judge and jury.

Within an academic institution and PHS, scientific misconduct investigations are conducted by administrators and scientists with expertise in scientific misconduct issues and the area of research in which the misconduct is alleged. The Departmental Appeals Board hearings may include scientists on the panel, as well as attorneys *(11)*.

Litigation is conducted in a public forum, while PHS investigations are generally confidential. Litigation is a public process. Any document submitted to the court or the opposing party during the course of a False Claims Act Case is publicly disclosed unless special arrangements are sought from the judge. Documents may be withheld from disclosure in litigation if they reveal the attorney's work in bringing the case, attorney-client communications, or confidential agency deliberations. Documents that affect individual privacy or commercial or trade information may be withheld or may reviewed in confidence by the judge.

Scientific misconduct inquiries and investigations are conducted through confidential proceedings. However, hearings conducted by the Departmental Appeals Board are open to the public, and some institutions also have scientific misconduct hearings that are open to the public. Any finding that an individual committed scientific misconduct is published as a notice in the *Federal Register*. Most, but not all, information relating to an investigation, if there is a finding of scientific misconduct, is available at the conclusion of the investigation through a request made under the Freedom of Information Act *(16)*. If there is a finding of no misconduct, information on the inquiry or investigation is not publicly disclosed.

Litigation is retrospective and remedial, while PHS procedures are largely prospective and preventive. Monetary damages recovered under the False Claims Act are intended to remedy past injury to the Government, not to prevent future injury. Damages may be calculated on the basis of all or part of the amount awarded to the institution, depending on the nature of the false claims. The court must also triple the amount of damages awarded to the Government, to account for any additional expenses the Government may have incurred in investigating the misconduct and any consequential damages, that is, damages that arise as a direct or indirect consequence of the misconduct, and must assess civil penalties for each false claim.

Conversely, administrative actions taken by PHS against an individual who has been found to have committed scientific misconduct are largely prospective and preventive. If the ORI determines that an individual has committed scientific misconduct, it may impose a variety of actions, such as requiring the institution to more closely monitor the researcher's future work, prohibiting the researcher from participating in scientific advisory groups for several years, or debarring the individual from receiving any Federal funds for a period of several years *(10)*. Even debarment from receiving Federal funding, the most serious administrative action available against an individual for scientific misconduct, is intended to protect Federal funds from future misuse *(17)*.

The agency within PHS that awarded the grant may also take prospective administrative actions against an institution or individual to protect the integrity of the scientific process and to exercise proper stewardship of Federal funding. For example, if a finding of scientific misconduct relates to the qualifications of an individual to conduct the project, the awarding component may withdraw its approval of the principal investigator or other staff named in the grant application, forcing the institution to name a new principal investigator or staff. Further, the PHS agency that made the award may withhold funds from any additional grants and suspend or terminate all or part of the grant *(12)*.

However, even though PHS actions are generally prospective, PHS does have the authority to take remedial administrative action against the institution for scientific misconduct when no False Claims Act case is filed. The PHS may administratively recover grant funds from an institution on the grounds that the grant funds have not been expended for allowable costs in accordance with Federal grants regulations, because they have not been used to further the purpose of the award, have been provided to a researcher who is not reliable, and have been wasted *(12)*. In such an

administrative action, the Government can recover funds that were misspent because of the scientific misconduct, but cannot recover expenses incurred in investigating and resolving the matter, or impose any civil penalties. The Government could potentially impose civil penalties on a grantee in a separate administrative action under the Program Fraud Civil Remedies Act *(18)*, but PHS has not, to date, imposed any civil penalties for scientific misconduct under this Act.

Litigation remedies benefit the Government and the relator, while PHS procedures primarily benefit the Government. In a False Claims Act case, the relator may continue to participate, or even litigate, the case, and may recover a portion of the monetary damages awarded to the Government and is entitled to compensation for legal fees and reasonable expenses if the suit is successful. If the claim is not successful, the relator must pay his or her own litigation costs, and may be responsible for the litigation costs of the defendant, but only if the court finds that the allegations were clearly frivolous, clearly vexatious, or brought primarily for the purpose of harassment *(3)*.

Under PHS administrative procedures, there is no formal avenue for the complainant to continue participation in a PHS inquiry or investigation or for the complainant to investigate the scientific misconduct allegations on his or her own. The complainant provides information to the institution or to the PHS and may be a witness at an administrative hearing, but does not participate in investigating the allegation. The PHS notifies the complainant of findings that relate to his or her concerns. There is no provision for compensating the complainant if a finding of scientific misconduct is made, but there is no financial risk for the complainant if there is a finding of no scientific misconduct. However, the complainant may be protected as a whistleblower against retaliation or other harm related to alleging scientific misconduct *(19)*.

Implications for Recipients of PHS Funds

The recent success of the Berge case under the False Claims Act for scientific misconduct shows that institutions may be held financially accountable under the False Claims Act for statements made by researchers and should ensure that attribution of research, data analysis, and data reporting in grant applications and progress reports to the Government are accurate. Individuals who engage in scientific misconduct may also be held financially accountable for research fraud committed against the Government.

The success of this case also shows that a public legal forum is available to a person who alleges that a researcher committed scientific misconduct, if the misconduct involves false claims to the Federal Government. The individual making an allegation can remain involved in the litigation of such a case, may receive a share of the Government's damages, and may be compensated for any harm that he or she suffered because of the misconduct as well as for the expenses incurred in pursuing the action.

Susan E. Sherman is a Senior Attorney at the National Institute of Health Branch, Public Health Division, Office of the General Counsel, Department of Health and Human Services.

Tearsheet requests to Ms. Sherman at Room 2B-50, Building 31, National Institutes of Health, 31 Center Drive, MSC 2111, Bethesda, MD 20892-2111; tel. 301-496-6043; fax 301-402-1034.

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